UNITED STATES
DEPARTMENT OF AGRICULTURE

Public Meeting on Current)
)
Thinking Egg Safety Standards)

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THE UNITED STATES DEPARTMENT OF AGRICULTURE

Public Meeting on Current)
Thinking Egg Safety Standards)

Federal Ballroom
Holiday Inn on the Hill
415 New Jersey Ave., N. W.
Washington, D. C. 20001
Monday
July 31, 2000

The meeting in the above-entitled matter was convened, pursuant to notice, at 8:35 a.m.

APPEARANCES:

LOUIS CARSON
CATHERINE WOTEKI
JOSEPH LEVITT
MARGARET GLAVIN
REBECCA BUCKNER
ALICE THALER
VICTORIA LEVINE
MARTHA WORKMAN
NANCY BUFANO
BOB ECKROADE
DAN McCHESNEY
CHARLES BEARD
RICHARD WOOD
MIKE OPITZ
PHIL DEBOK
CAROLINE SMITH-DEWAAL
JUDY RIGGINS
RICHARD BREITMEYER

APPEARANCES CONT'

AL POPE
DAN ENGELJOHN
MARY FANELLI
BOB BRACKETT
DARRELL WAGNER
RICHARD MATTEIS
JERRY CRAWFORD
MARTHA WORKMAN
DANNY HUGHES
DEANNA BALDWIN
KENNETH ANDERSON
JAMES SHIRK
MARILYN BALMER
ALICE WALTERS
JOHN MASON
KEVIN KEENER
CLARK MARINELLI

PROCEEDINGS

(8:35 a.m.)

MR. CARSON: Good morning. I'd just like to go -- my name is Lou Carson, I'm with the Food and Drug Administration, and I'd like to go through a few of the meeting format issues and then turn it over to Ms. Glavin to introduce our opening speakers.

Thank you for coming to the Public Meeting on Current Thinking Egg Safety Standards. Today, I'd like to first go through the agenda. Hopefully, each one of you picked up a package at the registration desk.

So, from 8:30 to 8:45, we're simply going to go over the administrative details, have a welcome from Dr. Woteki and Mr. Levitt. Then we're going to go directly into presentation of our current thinking documents, as you see here.

We are going to present the current thinking documents and we ask you to hold your questions until the open discussion period at 11:00, at which time we will then entertain all questions or comments. Then we'll break for lunch. And afternoon session will be open. If we need to extend the time for the open discussion, then we'll immediately start again with comments. But if we don't, then we won't need to.

For those of you who did register, and there is

still time if you would like to make a prepared statement, you may do so by registering at the registration desk. Currently, we have approximately five or seven people who have registered to speak.

Then at 3:00, we will have some closing remarks and then adjourning.

I want to advise you that the microphones are voice activated or sound activated. Even though it seems to be going in and out. So, if you speak to your neighbor at the table, there is a likelihood that the microphone may pick it up. So, be discreet.

This meeting is being transcribed. And if you have a comment or a question, we ask that you first introduce yourself and your affiliation so that the transcription service can pick that up and properly acknowledge your comments.

With that, then, I would like to introduce the deputy administrator for FSIS, Margaret Glavin.

MS. GLAVIN: Thanks, Lou.

Good morning, I'd like to welcome you all and thank you for coming. I've been in Washington long enough to remember when August was a slow time. Clearly, not the case any more for most of the people in this room. So, I know your time is valuable and we want to get right to the heart of the matter. There's a lot of material to go over

and discuss and get input on. So, with no further ado, I'm going to introduce our two speakers.

First of all, I'd like to introduce Catherine Woteki, who is our Undersecretary for Food Safety, and who has taken a great interest in this particular issue, egg safety, and will make a few remarks.

MS. WOTEKI: Thank you very much, Maggie, and good morning to everyone.

I also would like to add my words of welcome to you as we begin this public meeting on shell eggs and egg products that's being jointly sponsored by the two regulatory agencies with the greatest responsibility in this area, the Food and Drug Administration and the Food Safety and Inspection Service.

Today, you'll be hearing the agency's current thinking on national standards on egg safety. And I'd like to begin this meeting by talking a little bit about how we got to this point. What were the steps that led up to this meeting.

The story actually starts about two years ago in August of 1998 when President Clinton established the President's Council on Food Safety. That council has three co-chairs, the Secretary of Agriculture, Dan Glickman, Secretary of Health and Human Services, Donna Shalala and the President's advisor on Science and Technology, Dr. Neil

Lane.

The council was established to coordinate food safety for the country and to create a seemless science based food safety system.

The council is now in the final stages of preparing its strategic plan, which was one of the first things that the President directed the council to undertake. And the council is also working on developing a coordinated base budget for the food safety agencies.

The strategic plan is going to help us to set priorities to improve coordination and efficiency. To identify gaps in the current system and ways to fill those gaps, and enhance and strengthen prevention and intervention strategies. And the strategic plan, as well, is going to be what drives the base budgeting function.

Egg safety is an important component of that strategic plan. And it was placed on a separate, faster track in order to improve egg safety more quickly. Although, only an estimated one egg out of 20,000 produced in the United States contain salmonella enteritidis or SE. This involves a total of about 3.36 million eggs, annually, which have the potential to expose a large number of people to this pathogen.

We know that in regents of the country where egg quality assurance efforts have been the most intensive, that

SE isolation rates have been dramatically lowered. Thus, we have an opportunity to make a difference in terms of food borne illness by extending those approaches, nationally.

Therefore, in July of last year, 1999, FSIS and FDA committed to developing an action plan to address the presence and reduce the presence of SE in shell eggs and egg products, using a farm to table approach.

After obtaining public input to develop the plan, the Egg Safety Action Plan was announced in December of last year by President Clinton. And following release of the plan, the focus of the agencies and the council has now shifted to implementation of that plan.

In March and April of this year, the two agencies held public meetings to discuss that implementation and to get more comment on the implementation of the plan. Based on all of the comments that were forthcoming from those meetings, we're now ready to present current thinking on approaches to insure egg safety from farm to table. And that's what brings here today to hear your thoughts and comments and opinions about these plans.

I very much appreciate your participation and I look forward to hearing the discussions today.

Maggie?

MS. GLAVIN: Thank you, Cathy.

And now I'd like to introduce the director of the

Center for Food Safety and Applied Nutrition at FDA, Joe Levitt, who is also the co-chair of the meeting today.

MR. LEVITT: Thank you, Maggie.

Again, I guess I will now the fourth person to welcome you. So, with nothing else, you should all feel welcome at this meeting.

The -- to me, I'll only kind of go back one year since Cathy's given a broader background, and just say about a year ago, also in not a slow August, as I recall, we had a public meeting, not in this exact room, but in the general vicinity here. And what real -- I think two things really struck me coming out of that meeting.

One is that, number one, there already had been a lot of work done. There'd been a lot of work done by the producers, there'd been a lot of work done by the states, there'd been a lot of work done by the consumers, and we were by no means, starting from square one. Indeed, there seemed to be almost a resounding call from all quarters that we need consistent national standards.

So I think we took that as a real positive step forward. And I think the intervening year has largely reflected that.

Cathy is mentioned the action plan that was announced by the President in December. We then went and established working groups with a number of the state

representatives, a number of whom are here. Again, working with both agencies, you know, continuously. We've tried to reach out to the egg producers, reach out to the consumers, and including the two grassroots we had in Ohio and California.

And so that kind of brings us to today. We have what we call our current thinking document as the boilerplate for such document says. It is not the agency's final thinking. That's our current thinking. Although, on the other hand, what that means is were we to publish today, this is what we would publish. And so it's not just kind of our passing fancy. It is kind of where we have ended up following the last year.

This is both kind of what we think of as a 11th hour check. We are planning on going out with proposed regulations this fall. And, so, we very much are looking for everybody's input at this meeting.

I think our goal today is for the agencies to present and to try and clarify what is in the current thinking documents, what do they mean. We will do our best to respond to questions that are explanatory in nature. We will try not to be defensive, although sometimes one gets a little when it gets to that point.

But I think the goal over round, overall, is for there to be no surprises. We hope there are not major

surprises in the current thinking document for those that have been involved. And we hope when proposed regulations come out, again, there will be no surprises.

I think, finally, what I would say is that there -- this has been, while in the broad sense I think a fair amount of forward movement and togetherness, as with any issue, the details represent areas where people can go in many different directions. And what we're trying to do is come up with something, essentially, where everybody can live with. But, also, more than that, in a way that is going to significantly reduce salmonella enteritidis in eggs.

We do have the goal of 50 percent reduction in five years. We believe that that is achievable. This is a preventable problem. And with that, I think we should move forward.

My one last thing just thank all the people that have brought us up to this point, both the staff involved and the representatives from different groups that are here today that have really put a lot of personal time and effort in order to get us this far.

So, with that, let us, as we say, get on and we are, for the record, starting ahead of schedule.

The first part of the program is to deal with the on-farm production. And to present our current thinking on

the subject, we have Rebecca Buckner from FDA.

MS. BUCKNER: Can everyone see that or do we need to try to turn down the lights?

Okay, I'm Rebecca Buckner. I'm from FDA from the Center for Food Safety and Applied Nutrition. And the Office of Plant and Dairy Foods and Beverages.

And I'm going to describe FDA's current thinking for on-farm safety standards. And we arrived at this current thinking with input from our Egg Safety Standards working group and from comments that we received after the public meetings in both Ohio and California in, last spring.

And the documents that you all have in front of you outline our current thinking for the proposed rule, as Mr. Levitt just said, for on-farm standards that are scheduled to be published this year.

Who will be covered by the rule? Our current plan is that everyone who produces table eggs will have an SE risk reduction plan, which is basically a plan for reducing SE in eggs. We'll get into what the specifics of that in a minute.

Everyone who produces table eggs will be -- will have a risk production plan except people who sell -- farmers who sell directly to consumers. Like a roadside stand operator or somebody who has a booth at a farmer's market.

And also those producers whose eggs will go directly to some sort of a treatment like in-shell pasteurization or breaking plant.

For those who -- for those whose eggs will be treated that are in-shell pasteurized or go to a breaking plant, they must have refrigeration on the farm. They don't have to have a SE risk reduction plan. They only have to have refrigeration.

And the third thing is that everyone who produces -- everyone who sells eggs must register with FDA. And the reason for that is -- and this includes people who sell eggs to their neighbors or who have the roadside stand.

In the case of people who are covered by the rule, who have the SE risk reduction plan, they must register with FDA so that we can properly allocate our inspection, expenses and so that we know who's out there and we have a database that has the entire industry in it.

For those who are not covered by the rule, but sell eggs, we're having them -- our current thinking is to have them register so that we can provide them with educational materials on egg safety. But they will not be, in fact, covered by the rule.

The -- one of the proposed components of the SE risk reduction plan. Our current thinking is that the components would include the use of chicks and pullets from

SE monitored breeders. This is like the NPIP program. You must have a biosecurity plan, you must have some plan for rodents and pest control. You must do cleaning and disinfection if you are environmental test was SE positive. Cleaning, disinfection and depopulation. And you must use salmonella negative feed that meets the FDA Center for Veterinary Medicine standards. And you must have refrigerated storage on farm if your eggs are held on the farm more than 36 hours. And that's refrigerated storage at 45.

And in order to verify that the SE, that your SE risk reduction plan is working, we're proposing environmental testing, citizen verification step. And, basically, the environmental testing that we currently think we'll be proposing is one environmental test per laying cycle. An initial test at 40, when the laying hens are 40 to 45 weeks of age. And then an additional test if you molt at 25 weeks after the end of a molting process. And every time you molt, you have another environmental test. If you molt twice, you would have three environmental tests over the course of the life of that flock.

You can see from the little flow diagram here basically what happens. If your environmental test is negative, you proceed on with your business. If your environmental test is positive, you go into egg testing. If

your egg testing is negative, then, once again, you proceed on with your business. If your egg testing is positive, divert your eggs. And that is divert your eggs for the life of that flock, except there will be protocols for you to test back off of -- into table egg production.

So, but if you choose not to take one of those testing protocols to get off diversion, then it's diversion for the life of that flock.

Finally, two, two other points on our risk production. I mean, on our -- yeah, our risk production. Administration of the plan. You must have a trained individual to administer the plan. And we are intending to provide training courses for industry. And we hope to do that as much as possible in collaboration with industry and the states and academia.

And, also, there're record keeping requirements. You retain a copy of your written SE risk reduction plan and also records indicating compliance with the various components of that plan like your rodent and pest control, biosecurity, cleaning and disinfection and your testing results.

And that, basically, sums up the sort of high points of our farm current thinking. And as has been stated before, this is current thinking, it's not final. And we're very much looking forward to getting your feedback on

propose for on-farm.

Thank you.

MS. GLAVIN: Alice Thaler of FSIS is going to walk us through the current thinking on regulations for shell egg packers.

MS. THALER: I'm going to cover the shell egg packers and then right after that, you'll get the egg products processing.

We define shell egg packer as anybody who packs anybody else's eggs. Obviously, you pack your own, as well. But if you also pack other people's eggs, shell egg handler will fall into that.

If you're familiar with what we do in meat and poultry, you're going to hear a lot of similar thinking in our current thinking for eggs. So many of the changes that we're proposing for shell egg packers are to put the regulations that we're thinking about proposing for packers in line with what we already do at FSIS for meat and poultry. The same kind of thinking.

So, the first is sanitation standard operating procedures which are currently in 9CFR416. So a lot of the same thinking that's for meat and poultry, we'd like to do the same thing for meat and poultry, we'd like to do it for eggs.

Thinking about HACCP, that shell egg packers would

have to have a HACCP plan. That's our current thinking at this point. And if you look at 9CFR417, the same kind of thinking that we use in meat and poultry, we want to put parallel thinking in place for the shell egg packers.

This one subject of prohibition on repacking was discussed a lot from the time we had the standards work group meeting, people pulled together from the states, from FDA, FSIS and APHIS and AMS. And seemed to be a lot of consensus on the need for a prohibition on repacking.

Meaning if eggs had already been packed for the ultimate consumer and had been shipped for retail and for whatever reason one got broken, that there was some reason that that egg carton couldn't be sold as is, that it just isn't worth the risk to try to repack them, worry about the date of the eggs, worry about how they're handled until the point they are repacked. And we did get some information that some eggs seems to travel all over the country for weeks and weeks, and that's just something we seem to have a lot of consensus that we should just discontinue.

We're going to take anything that we write for shell egg packers and do it as performance standards. That's our current thinking. Performance standards, they described the desired outcome and they also provide flexibility. So, instead of giving very specific -- for examples, temperatures of water or times, ph, we'll try to

describe it as a more general what are you trying to accomplish. So then the industry can have documentation to support why it chose the method that they choose to meet the performance standard.

Of course, if we're going to do SSOP's and HACCP record keeping is a big part of that. Do want to avoid any duplication of record keeping requirements, so we're working very closely with FDA to try to avoid that.

Interested in information that would help document the movement of eggs, just about anything you could imagine that would help you tell where that egg came from and how it got to that point when you're looking at it possibly for a trace-back or some other problem, that there are records that you can tell exactly how that egg got to the point that -- so, we're looking at things like date of lay, information like that.

Obviously, the standard documentation for SSOP's and HACCP. And then documentation of labeling.

Okay, and this just summarizes, again, the current thinkings. And the coverage for these again, all shell egg packers which were defined in the first slide, would be under the things I just talked about. And that two other things, one's like an exception and one's an exemption I wanted to highlight. And that's why it's listed separately in your document.

Talking about registration, again. Shell egg handlers except if you're a producer packer, the annual egg production from a flock of 3,000 or less who grades impacts eggs for the ultimate consumer, don't have to register if you're already registered with FDA and you don't have to register if you're a hatchery.

And then the last, that's just a little different that I put it separately. Was shell egg producer packers with an annual egg production from a flock of 3,000 or fewer hens who also does not pack for other producers, then that's the standard exemption under the EPIA that we are thinking about that we have to develop our proposed regulations with that in mind because it's already in the EPIA. And these people would have exemption from temperature and labeling requirements.

And I think we ended the egg shell process products.

This mike's going to drive everybody crazy.

MS. GLAVIN: Let me suggest. Would it be easier if you sat and used the mike here? Because that mike is really -- it's, I know it's very hard on the presenter, it's also hard on those of us who are listening. Can -- is that a problem for you?

FEMALE SPEAKER: Not with me.

MS. GLAVIN: Okay. Then, Victoria Levine, from

FSIS is going to be very accommodating and flexible in her presentation, and she's going to make a presentation on egg products processing. And we'll just forget about the other mike.

MS. LEVINE: Not only am I going to be accommodating, but I have good news and bad news. We'll start with the bad news.

I hate to be repetitious and boring, but what I'm about to say sort of mirrors the previous presentation. That's the bad news.

The good news if you weren't paying attention, you get it again.

For egg products processors -- these are breaking plants, we intend to follow what we've done with meat and poultry. We think that, just like with meat and poultry, just like with shell eggs, we would start off with sanitation SOP's and we would then move to HACCP. So, 9CFR, Part 416 and Part 417, those would be the requirements that egg products processors would have to meet.

The prohibition on repacking which applies to shell eggs, comes into play here because the one place -- well, not the one, but one of the places and the primary place these eggs are going to go, is going to be to the egg products breaking facility.

So, if for some reason your eggs have been shipped

for retail sale and for some reason they can't be sold, the store doesn't want to sell them, whatever, well, you can't repack them and send them to let's say, another Giant, Safeway, whatever. You can send them to the egg products breaking plant.

We're also going to probably go with performance standards for the lethalities for egg products, dried egg products, pasteurization of shell eggs. They're going to be some probably, you know, cooling, storage performance standards. Again, they all -- they tell you where you need to be, but not how you get there.

And, again, the record keeping requirements will be those of SOP's, HACCP. There will also be some in terms of where did the eggs come from, how old were they when you got them, how long have you held them, things like that.

And, also, for labeling, again, we're going to try, we think, and match up with what we have or meat and poultry, which actually means a reduction to some degree in the requirements. We'll be doing away with prior approval of labeling so lots of things will be generically approved. And, again, there're some minor record keeping requirements with that.

And that is pretty much what we think we're going to do.

MS. GLAVIN: Thank you, Vickie.

Martha Workman, also of FSIS, is going to talk about a baseline project which is very much in our current thinking. And this is a baseline project for egg products.

MS. WORKMAN: The purpose of establishing a baseline for egg products is to develop performance standards for the pasteurization of liquid eggs and egg products.

We propose to conduct a survey to collect data on salmonella species with stereomonasetargenies, campylobater, clostridium perfringens, staph aureus and generic E. coli.

In addition, we would be doing APC's at 35c and total coloform counts. Why are we doing this?

As you know, we have sponsored public meetings and the information producing or eliminating the risk of SE in shell eggs and egg products. That's the purpose. In the end, we also had a meeting with industry in which they requested that we conduct this survey.

The organisms that we have selected are the following: Again, salmonella lystermonstogenies, campylobacter, clostridium perfringens, staph aureus, and also, additional indicator task, E. coli total coloforms and aerobic plate counts.

Our sampling program, we have conducted baseline programs in the past for meat and poultry products. This will be similar. And we'll be using our MLG, microbiology

laboratory guidebook, an additional methodology published in the baseline.

The participants, about 80, 60 egg breaking establishments, the members of United Egg Association, United Egg Producers and Independent Operators.

This paper is so current that it wasn't included with the other papers that you have. We are making changes and would appreciate your input.

MS. GLAVIN: Thank you, Martha.

Going to turn it over to my co-chair.

MR. LEVITT: Okay. Thank you.

And, finally, for our final presenter from FDA, Nancy Bufano, who will talk about egg safety at retail.

MS. BUFANO: Okay. The retail segment is the last segment in the front table continuum. And I'll present FDA's current thinking on the retail standards for those retail establishments that serve or prepare eggs.

We arrived at these standards -- well, these standards are taken or adapted from FDA's 1999 Model Food Code. The food code is not a regulation or a rule, but, rather, it's reference that's published by FDA to guide retail outlets such as restaurants and grocery stores and institutions like nursing homes, hospitals and prisons on how to prevent food borne illness.

It consists of model requirements for safeguarding

public health and insuring food is unadulterated and honestly presented when offered to the consumer.

First, I'll talk about our current thinking for all retail establishments. Any retail establishments that uses raw eggs, the eggs would have to be transported at an ambient temperature of 45 degrees Fahrenheit or lower. They would have to be clean and sound. And they would not be allowed to contain more restricted eggs than currently allowed in U. S. Consumer Grade B.

Also, for all retail establishments that use egg products, liquid, frozen and dried egg products, the products would have to be in pasteurized form. Specifically for retail establishments that serve at-risk consumers, and here we're talking about, for example, hospitals, nursing homes and day-care centers. These establishments would be required to substitute either treated eggs or pasteurized egg products for raw eggs in certain menu items.

Those items being items that either contain raw egg ingredients and are not subsequently thoroughly cooked, or -- and there's an error here I just noticed in your -- in your handouts. The second bullet -- menu items that are prepared by combining and holding eggs prior to cooking. That should be prior to cooking.

And then, lastly, menu items that are prepared by holding eggs following cooking and prior to service. These

last two, those last two items relate to the cooling of eggs. Commonly called cooling of eggs.

And, lastly, our current thinking on retail establishments that serve the general public. We're currently considering auctions for those retail establishments for serving ready to eat foods that are either prepared with raw or undercooked eggs and are not subsequently thoroughly cooked.

We're also considering codifying those times and temperatures in the model food code for cooling and holding foods containing raw or undercooked eggs. They're not thoroughly cooked.

And, again, we have received some comments, but we would appreciate your input and additional comments on retail standards.

MR. LEVITT: Okay, thank you very much for all the speakers, whom we seemed to have survived the microphone. We're also trying to get the room cooled down a little. But it does seem at least not hotter than it was when we started, so maybe we're making some progress there.

What I think we will try to do next to kind of get everybody's head set in how to interact and how to participate in the meeting. Maggie and I just consulted.

We will go through the same three parts of the farm to table continuum. We'll go through on-farm. So,

we'll do that next. Then we'll go through packers and processors, and then we'll conclude with retail. So, we'll try to get all the discussions with those sections in that period of time.

And I think within those, it's probably just starting with on-farm, Rebecca will now have the benefit of this mike instead of that mike.

I think it's probably best to start with questions of clarifications and then we'll get into opinions of what you think works, what you think still needs some revision.

Yes, please. And please identify yourself.

MR. ECKROADE: I'm Bob Eckroade from the University of Pennsylvania. I have a question about the definition of salmonella free feed. As it's stated in there, it says something to the effect of salmonella free feed in the foreign farm program.

MS. BUCKNER: It's salmonella negative.

MR. ECKROADE: Negative. So that implies feed has to be tested, then?

MS. BUCKNER: Well, Dan McChesney is down there at the --

THE COURT REPORTER: I'm sorry, who's talking now, please?

MS. BUCKNER: I'm Rebecca Buckner, I'm sorry, from FDA.

Dan, do you want to handle that? He's from CVM. And they're the ones who establish the standards.

MR. MCCHESNEY: The answer, Bob, is -- the answer is that --

THE COURT REPORTER: I'm sorry, who's speaking?

MR. MCCHESNEY: Dan McChesney, Center for Veterinary Medicine.

MR. LEVITT: The answer is no, feed doesn't have to be tested by the producer or the on-farm egg user.

The answer is no, it doesn't have to be tested by the producer or the on-farm user. We would like to see it either come as a guarantee from a feed manufacturer or normal guarantees or commerce. And I think it's being done a lot within the industry now. People are requesting feed.

And our definition, for those of you that are interested are, in FDA parlance, it would be ten sub-samples testing negative. That would be 25 grams of feed testing negative for salmonella using a culture method. I think everyone else would say it would be ten normal samples that you would take. And that's on a lot. And we have yet to define lot and we will leave that to the producer.

I mean, I think our thinking is is that a lot would be a day's production or if you're making a starter type of feed or finisher type feed or something -- when you change feeds, that would be a distinct lot in our view. Or

if it was a day's production.

And, Bob, just for, again, to be sure we're clear, that testing is done by the seller or the buyer?

THE COURT REPORTER: I'm sorry, who's speaking?

MR. LEVITT: Sorry, Joe Levitt. That testing, is it to be done by the seller or by the buyer?

MR. MCCHESNEY: It would be up to the choice. I would think it would be done by the seller or be in by contract. I mean, I think the overring thing here is that we're -- we meaning FDA, CVM would like to see product -- if we were to show up and take a sample of the feed, we'd like the feed to be negative. Now, how they get about that and who tests it and who guarantees it, I think that's an issue for the users of the feeds, the producers of the feed.

MR. ECKROADE: If I can follow up since I had that question, please, well, I have some great concern about the requirements for any regular testing on lots of feed simply because of the kinds of volumes we're talking about in the sense that even the largest batch that would be mixed at a feed mill, if that were a lot, and I understand you said you hadn't defined lot. Would be an enormous lot of testing if we're using that as the criteria, as opposed to, perhaps, what we've all encouraged over the years is the use of a salmonella reduction program by the feed mill for the ingredients, the APPI. And I'm hoping that we can avoid the

inclusion of very specific testing requirements on batches of feed, not that we can overlook the need to assure ourselves that we're doing everything we can to keep salmonella at the lowest level possible.

MR. MCCHESNEY: I would agree with that. Dan McChesney, Center for Veterinary Medicine. I would agree with that. And that the goal here is not to test every lot, but the goal is for the person making the feed to have a control program in place. And if it's a quality assurance program or GMP's or it's HACCP, I think it's our view, like any other food product, that we don't end test every product we eat in this country. There's a manufacturing step and they control the process. And that's what, in my view, the manufacturer needs to do. Is control the process.

MR. LEVITT: Thank you. Are there questions, first, for clarification? Yes?

MR. BEARD: My name is Charles Beard with U. S. Poultry and Egg Association. It deals with the same issue. Do you mean salmonella negative or salmonella enteritidis negative?

MS. BUCKNER: Rebecca Buckner, FDA. It's -- the standards established by CVM are for salmonella negative feed. And so since at this point we were going with standards that had been established, it was just salmonella.

MR. MCCHESNEY: Dan McChesney, Center for

Veterinary Medicine. I can maybe follow up on that a little bit.

There is a current regulation that sometimes we overlook when we just focus on in this forum here, focusing on eggs. There is a current regulation, 21CFR500.35 that states that feed or feed ingredients contain salmonella is considered adulterated under the Food, Dairy and Cosmetic Act.

So, we are sort of, you know, like to uphold the regulations. If, in fact, for this program, you'd like to look at SE, I mean, I think that's within the perview of this. But there is that other requirement.

Now, SE, and I'm sure Charles probably knows this, is that it's rarely been isolated from feed and where the flock hasn't been already positive for some other either environmentally positive or other thing. We have isolated one from soybean meal, meaning FDA has. And it may have been isolated a couple times over the years in duck feed, but I think USDA in the early '80's and Dr. Mason, here, maybe remembers the exact date or something. At least the years or something. But he's the wealth of knowledge over here.

So, I think SE is very unlikely that you might not get a seed. It's going to be easy to do. The other point is is that the data FDA has from the CVM side is that if you

look at ingredients, the salmonella levels are reasonably high in those. If you look at finished feed products, especially ones that have ? it's very, very low. And the history and the literature says over 20 years, it's maybe five or ten percent.

So, I think it's achievable goal to have salmonella negative feed. And it's easily, I think, achievable to have salmonella enteritidis negative.

Thanks.

MR. BEARD: Mr. Chairman, would you accept a comment other than a clarification?

MR. LEVITT: Yeah, if it's on this point.

MR. BEARD: It's on this point.

MR. LEVITT: Sure.

MR. BEARD: I know of no evidence and -- Charles Beard.

I know of no evidence that really indicates contaminated feed has been a significant risk factor in the area of salmonella enteritidis, number one.

Secondly, Dan, as you well know, the APPI people, the poultry by-products people, have had a very, very difficult time providing salmonella free by-product. They just have not been able to do it and they've been trying for years.

Layer feed is not pelletized, so there is not that

final heat step in the treatment of completed feed. So, it's going to take a lot of re-engineering of the feed process for the layer industry to pelletize feed. And that's the only hope they have of getting salmonella free product because their basic ingredients are not salmonella free.

So this -- you need to put a lot of thought into this requirement. This is going to be very difficult to meet. And I contend it really has nothing to do with salmonella enteritidis in eggs.

MR. MCCHESNEY: Okay, Dan McChesney, CVM. And that may be true, Charles, but I guess as a producer, I would say if I had my SE negative flock and I was doing everything environmental control, I brought in positive feed that had SE in it or something, I may have SE and contaminate my environment and my birds and eggs were clean. And that ? to this plan, I would be kicked into a whole 'nother spectrum of requirements with my eggs and reduce, really reduce the marketability of my eggs for something that was -- something that could have been controlled. And, you know, I'm not sure how industry would like to deal with that. I mean, this puts some light in my view at great risk by not addressing the feed issue.

MR. BEARD: Charles Beard again. I really didn't know we had a feed issue with salmonella enteritidis, Dan,

and I guess that's my point.

MR. MCCHESNEY: Okay. Well, Charles, maybe we don't, but is there anyone that's in the producer willing to put their rights on line and take that chance? If they are, then they probably need to come forward and say that and say we don't care about feed 'cause we don't think that's a risk factor and we're willing to bet our eggs and the price of our eggs on that in diversion.

MR. LEVITT: Okay. Again, I think for purposes of today, I think we've had a good, healthy discussion of that issue.

Are there any other points on the salmonella negative feed issue? That despite my efforts to do questions and then comments, maybe it's better to do the issue together as we get into it.

Anything else on that particular issue? Yeah?

MR. WOOD: Richard Wood of FACT, Food Animals Concerns Trust. I just want to say I appreciate this issue being placed on this list. It's an issue that hasn't been fully debated and discussed for some time, at least within FDA circles, and I think it does need to be considered once again.

On our farms, we do pelletize our feed for layers and we do test that feed. And we've had very low, very infrequent positives. And I think that this question

deserves review for the research and a way of looking at how to implement a process where we're not feeding positive feed to birds that we want to produce a negative product.

MR. LEVITT: Um-hmm. Yes, over here.

MR. OPITZ: And in the same context --

MR. LEVITT: You need to identify yourself.

MR. OPITZ: Michael Opitz, University of Maine.

I just like to point one great technical difficulty. Feed is normally not stored. Feed which is mixed today is being transported and put into sylos the same day. Test results will be available at the earliest about a week later. So, any test result will be available only in retrospective. I don't know how that could be combined so it makes sense.

MR. MCCHESNEY: Dan McChesney, NFDA. I think, Mike, on that point, it really goes back to my answer to Bob Eckroade. And that I view it as controlling the process by the manufacture. And I think you can say that for a lot of the food products, whether animal food products or human food products. That we're not in product testing, we're controlling the process. And that my view in controlling this, and I think is CVM's view in controlling it, is that we need to control the process by which feed is made to control any salmonella in it.

So, it's not an in product testing issue, it's

control entire process. And if you need to test it on a daily basis to do that, then you test it on a daily basis. If you need to test it on a weekly, weekly. If you need to do it monthly, monthly. Or six months, do it. Whatever it takes to give you, the manufacturer, the assurance that you're producing a quality product.

MR. LEVITT: Yes.

MR. DEBOK: Phil Debok with the Pennsylvania State Department of Agriculture.

I still need clarification. Is there a program -- I mean, I realize there's a requirement that it be free of salmonella , but is there is -- the CVM have a program, a certification program at this time that is available.

MMR. MCCHESNEY: No. In fact, I'm not sure there's any certification programs within FDA. We don't really certify.

MR. DEBOK: So, who is it up to to make that --

MR. MCCHESNEY: It's up to industry. I mean, industry is making the product and it's their responsibility to produce a safe product. Now, if we come in and test, is it there? Yes. Will we take action? We might take action. We have taken action against salmonella on positive. There have been on -- products have been brought into the home. There's a continuum here.

MR. DEBOK: Well, Phil Debok with the Department

of Agriculture again, Pennsylvania.

The argument or the question or the concern is that we're going to have a regulation that requires that this fee be from, quote, an approved source or certified source. I mean, that's the implication here, and yet --

MR. MCCHESNEY: The implication is that there's already --

MR. DEBOK: The regulation --

MR. MCCHESNEY: That regulation is already on the books.

MR. DEBOK: There's a requirement that it be free of salmonella negative.

MR. MCCHESNEY: Yes.

MR. DEBOK: So, it's going to be -- who is it going to be up to to determine that from the standpoint of this producer, this small producer that's out there that's required to buy this feed that's, you know, quote, from an approved source? And you're saying, well, he can test it or the company can test it, but somebody's going to have to test it. That's what we're hearing and it gets to be very difficult to regulate that. That's our, I guess, my concern.

MR. MCCHESNEY: And I don't know that anyone -- you have to -- I go back to do you have to test each lot, and the answer is no. But the manufacturer has to do it.

I mean, the same thing for any product we eat. And we need to step back here and think that we haven't divided out food in the Food, Drug and Cosmetic Act as food for humans and food for animals. It says food for man or other animals. It's all under the same regulations and we cannot step back from that. We need to realize that. Or we need to change the act.

Caroline.

MS. SMITH-DEWAAL: Caroline Smith DeWaal, Center for Science in the Public Interest. And I wasn't going to weigh in on this, but I think I will.

I appreciate the fact that the Government agencies are looking at existing regulations and applying them to this new program to reduce the incidents of salmonella enteritidis from eggs. So, I think that that -- it's actually very satisfying to hear that there're already regulations and requirements on the books that chicken feed for layers be salmonella free. And that that now is going to be brought into and applied to this program.

The bottom line for HACCP implementation, and this goes for whether we're dealing with small meat packers and ground beef operators or egg producers, is that they need to source their material. And as a buyer of feed, you have a certain amount of market power to ask the producer to tell you whether the feed has been tested, to tell you whether

steps have been taken and the process has been implemented to control or eliminate salmonella in the feed.

The fact that those things don't exist today, shouldn't be a bar to these kinds of protections. And the industry will have to develop those programs and to enforce those programs. So, I'm, as a representative of consumers in this process, I think we're very satisfied to hear both that regulations currently exist and that they're going to be applied in a new way in this program.

MR. LEVITT: Any other comments on the salmonella negative feed issue? Okay. Thank you.

Are there other -- I suspect there are -- other requests for clarification?

Yes, Caroline.

MS. SMITH-DEWAAL: Caroline Smith-DeWaal, Center for Science in the Public Interest, and I only have three requests or clarification.

MR. LEVITT: Um-hmm.

MS. SMITH-DEWAAL: First is why is the Government exempting three producers with 3,000 layers or less? What part of the market does that represent, why do we think these people have, don't have a public health concern related to their product? Why are -- why was that number chosen? What is the basis?

MR. LEVITT: Judy.

MS. RIGGINS: Judy Riggins, FSIS.

There's currently an exemption in the Egg Products Inspection Act that exempts all egg handlers who have fewer than 3,000 flock. Number in their flock. And, so, we have, because of the statutory exemption and our current thinking, we would exempt those.

Now, we don't intend to exempt them from education, though. We do intend for all of those who have fewer than 3,000 flocks to do an extensive education program using the network that we established for the small and very small HACCP implementation and to extend that, work with the states to provide the educational materials so that all egg handlers will have the information.

But in terms of covering them under the requirements and enforcement, we would have that exemption in the act.

MS. SMITH-DEWAAL: Do we know what percentage of the market that represents?

This is Caroline Smith-Dewaal.

MS. LEVINE: Victoria Levine, FSIS. It's very small. It's one to two percent.

MS. SMITH-DEWAAL: And we hope in your proposed rule making you might outline the public health impact that those producers have in today's market.

My second question is on the testing frequency.

What is the basis for the current thinking that you should do environmental testing at 40 to 45 weeks of age and 25 weeks at the end of each molting? How did you come up with those figures? Have we pilot tested any other frequencies or time periods for testing? Why are we only doing one test per laying cycle?

Those are my questions at this point.

MR. LEVITT: Okay. Rebecca Buckner?

MS. BUCKNER: Thank you.

MR. LEVITT: You were expecting that question.

MR. BUCKNER: Yes, I was.

The testing is a verification step that your plan is working. And the 40 to 45 weeks is one of the peak production times and we thought that would be an appropriate time to assess whether or not your poultry health environment was, in fact, SE negative.

We -- as I said, it is a verification since testing will not, in effect, reduce any SE that's there. We chose to focus on the management tools that would, in fact, reduce SE rather than requiring a lot of testing.

MS. SMITH-DEWAAL: Have -- what percentage of the eggs would we actually reduce going to market from an SE positive flock if that's where the testing point is? Have we pilot tested any programs or -- for example, I mean, I know we've got a Pennsylvania Quality Assurance program,

which was a pilot test for this kind of system. Do we have any other sense of where the best point of testing a flock would be in order to divert the maximum number of contaminated eggs from the consumer market?

MS. BUCKNER: Rebecca Buckner, FDA.

No, our main source of data is the PEQAP program. And other than that, we have not done pilot testing or anything.

MS. SMITH-DEWAAL: And what about the 25 weeks after molting?

MS. BUCKNER: Oh, we were trying to pick a comparable time in the second laying cycle as the 40 to 45 weeks.

MS. SMITH-DEWAAL: My recollection, and it's always a little foggy because I deal with too many foods in my job. But my recollection is that FSIS came out with a statement or a letter last year talking about the issue of forced molting and the impact on SE, the SE infection rate of the eggs from an SE infected flock.

Could someone from FSIS perhaps talk about what your findings were and why that was a concern?

MS. RIGGINS: Judy Riggins, FSIS.

The letter that you're speaking about I believe is an August, 1998 letter in which we made the statement that, that withdrawal of water and withdrawal of feed could lead

to increased shedding of SE.

The -- understand that there is -- you know, that letter is two years old and that there is ongoing or current on -- and -- yeah, ongoing research on that issue. And we, we also said in that letter we don't have jurisdiction to take any type of action regarding that.

So we are at this point, to revisit issues that we raised in that letter. If the research shows differently, we certainly do what we can to, to restate or to modify that letter so that our position is based on the current data.

MS. SMITH-DEWAAL: Well, two questions. Who is doing the research and who has jurisdiction?

That's Caroline Smith-DeWaal again.

MS. RIGGINS: We know that there is investigation -- I'm sorry.

MR. LEVITT: Judy, the first question was who's doing the research.

MS. RIGGINS: ARS and the industry are currently doing research. FDA has the jurisdiction.

MS. SMITH-DEWAAL: Okay. The -- well, I guess I'll save my last issue for the next segment. Thank you.

MR. LEVITT: Okay, thank you.

Other requests for clarification. Yes, from California.

MR. BREITMEYER: Richard Breitmeyer, California

Department of Food and Agriculture.

Under the SE risk reduction plan, it says components may include. Is the intent of the rule going to be to allow the producers to pick and choose, or will these be mandated?

FEMALE SPEAKER: No, they'll be mandated.

MR. LEVITT: Other questions for clarification. Yes.

MR. WOOD: I'm the, the manager --

MR. LEVITT: Identify yourself.

MR. WOOD: Richard Wood with FACT. Cleaning, disinfection of poultry house if the house or eggs are SE positive, then there was -- it's my understanding, I know we do on our farms, after every flock, the custom is industry-wide that cleaning and disinfecting takes place. I'm wondering why, if that is true, why that was not on the list since that's already being accomplished.

And, secondly, as a verification steps that cleaning, disinfecting has been adequate, I'd like to suggest that there be a test following cleaning and disinfecting, particularly if the flock has been positive, the previous flock.

MS. BUCKNER: Rebecca Buckner, FDA.

As far as the cleaning and disinfection only if the house is positive, we certainly would encourage

everybody to always to clean and disinfect their houses at depopulation. However, because this is a rule specifically targeted to SE, if you have an environmental test which is shown that you don't -- the test results have shown that your house is SE negative, then we have no reason to make you clean that house to control SE.

Although, as I said, we certainly would encourage people to do it for a variety of reasons. And we certainly would consider your suggestion about the testing.

MR. LEVITT: Yes. Sounds like a follow-up.

MS. SMITH-DEWAAL: It is a follow-up. In that instance, aren't you treating the end product test not as a verification test, but as the final answer that the house is not infected?

MS. BUCKNER: For the purposes of requiring cleaning and disinfection.

MS. SMITH-DEWAAL: That seems verification -- testing for verification is not an absolute. It is a check on your system. And it seems inconsistent from the straight HACCP standpoint that then that test would be the sole determinate on whether you would do cleaning and disinfection. Just food for thought.

MR. LEVITT: Other questions. Yeah, please.

MR. POPE: If I could go -- Al Pope, United Egg Producers. If I could go back just a minute on the 3,000

exemption, just for an explanation, if I can.

First of all, the percentage would be much less than one percent. Just to make sure that we're clear on that.

The other thing is that it was not -- this was not a request by the industry 'cause the industry didn't like the exemption, either. I think it was one that OMB imposed both on USDA, FDA and the industry as a matter of efficiency and the fact that the risk was so low because of the small amount that it represented.

MR. LEVITT: Other questions for clarification? Yes, please.

MR. DEBOK: Phil Debok, Univers- -- State Department of Agriculture. Get confused with my distinguished colleague here.

But the clarification on the 3,000 exemption, that's for the shell egg packers, right? I mean, the packer --

MR. LEVITT: That's right.

MR. DEBOK: Producer packer, the small producer -- I mean, this producer packer still has to have the on-farm requirements, right?

MR. LEVITT: Yes.

MS. BUCKNER: Yes.

MR. LEVITT: Yes, please.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

With that exemption, is that that they just don't have to register or are they totally exempt from all the requirements?

MR. LEVITT: I'll ask Judy Riggins.

MS. LEVINE: Victoria Levine, FSIS. They are exempt from all the requirements. It states that in the act.

MS. BALDWIN: And if they are exempt, many states already regulate the ones with less than 3,000. Would that have any impact on our state regulations?

MS. LEVINE: No.

MR. BEARD: Charles Beard, U. S. Poultry.

For clarification, now, FDA has one set of requirements for the small producer and FSIS has another. They're exempt by FDA?

MS. LEVINE: We're --

MR. BEARD: Exempt by FDA, they are exempt by FSIS, is that correct?

MS. LEVINE: Yes.

MR. BEARD: Okay.

MR. LEVINE: They're -- we're talking about once the eggs get to the packer, that's when the 3,000 kicks in. That's when FSIS regulations kick in. Prior to that, it's

FDA jurisdiction.

MR. BEARD: And FDA does not exempt them.

MS. LEVINE: That's correct.

FEMALE SPEAKER: Right.

MR. ENGELJOHN: This is Dan Engeljohn with USDA, FSIS. I'd also like to add a clarification just so that in case this comes up again today.

The statute doesn't specifically mandate that we offer that exemption. It allows for it. And so in the comment period, we would certainly make that an issue that you can comment on. And we welcome input.

MR. LEVITT: Well, I think at this juncture, I should the compliment staff for being so clear with the current thinking document. Because this is actually, I think remarkably few number of questions for clarification on on-farm.

But let me then re-open it up for on-farm in terms of comments, good, bad, indifferent. It's okay to say if you like something.

MR. POPE: I would have maybe just one question. If -- Al Pope, United Egg Producers.

One question. On the 25 weeks, I'm not questioning that it should be done. The 25 weeks after the end of each molt, I just wonder is there, is there some science on that or is that just in sort of the same kind of

relationship as the 40 to 45 week was established?

MS. BUCKNER: Just the same kind of relationship.

MR. POPE: Yeah, okay. All right, yeah, just checking.

MR. LEVITT: Richard.

MR. WOOD: Richard Wood with FACT. I was going to save this for comments later on when we have our five minutes. But I would encourage you to take a look at PEQAP protocol where it calls for five to seven weeks after return to feed.

Generally speaking, we think the protocol and a lot depends on how much the mays become musts. Because right now, there's a whole list of components that are we may consider or we may include. But that, taking the mays into musts for the most part, doesn't have to be everything on the list I think. And taking a look at the protocol, it is a fairly strong proposal that certainly warrants further discussion and refinement. And we're glad to see that the FDA is taking this step.

There are several items that are not included on the list which I think we'll talk about later on. One has to do with who implements this plan. There's no discussion about that.

The second has to do, and perhaps this is later on in another section, has to do with the carton label. And

there're other exceptions like that that need discussion and review at some point.

So those would be some of our concerns.

I think as a bottom line, the FDA and FSIS, particularly with on-farm, the FDA needs to be commended for beginning this program on the farm. Their egg safety plan on the farm. As opposed to at the packing house door where other HACCP plans have initiated their efforts.

And the fact that with the cooperation of industry and consumers, the FDA is initiating this egg safety plan within the farm gate is to be commended. And we look forward to strong steps in that regard.

MR. LEVITT: Okay. Thank you.

Other comments, reactions? Please.

MR. OPITZ: My comment -- Mike Opitz, University of Maine.

My comment goes to what's the intent of egg testing and egg diversion. The question I have was there any intent to compensate or indemnify those producers that might be severely economically impacted by such a measure?

I have severe reservations and concern about egg testing and conversion -- and diversion because I think that's a quick fix approach to a very complicated problem that cannot be resolved from one flock to another quite easily. And those who have dealt with that problem for 12

years knows how difficult, extremely difficult it is to solve those problems on site.

And it is not difficult only because the supporting science isn't there. Cleaning and disinfection are two words. But the real science behind it is extremely difficult at the level of mass production produce ? population today.

The same thing is rodent control. Rodent control is a moving target all the time. It's a science to really implement and to achieve those goals which we have set out to achieve is extremely difficult. And it is easy for us to say, yeah, that is what we want to do. But, now -- and, therefore, I think the major efforts should go towards resolving some of those very difficult issue.

Raising poultry on a farm is a very difficult thing. You think of the chicken house as a food processing plant. It's a farm. Animals are rumbling in the ship. There are flies around, there are rodents around. And this is a reality which we have to recognize. That's number one. So we have to deal with this. And if you very thoughtfully and put science behind a regulation which we intend to implement.

But let me get to egg testing and conversion. And diversion. I have three concerns with that.

Number one, I feel the egg testing will produce

arbitrary results which do not allow a fair implementation of those measures which we want to do. For the simple reason we hear one per 10,000 or one per 20,000 eggs is contaminated with salmonella. We make an assumption that, first of all, the contamination or the production of this contaminated eggs in the house are on their normal distribution in house, which is not true.

Number two, we make an assumption that infected hens lay at the same level infected eggs. Which is not true. And, therefore, naturally, our results would be very arbitrary. And it's a kind of a Russian roulette, those which are caught are in trouble, those which slip through, was the lucky ones. We haven't achieved, really, very much. That's number one.

Number two is even if we find positive eggs, there's no -- there's nothing at this moment where we differentiate, number one, what level of contamination do we have. Was it the single egg which we found? Is there a difference in the virulence of salmonella enteritidis? And we know there are different strains out there. Some are very harmless and some are much more virulent. There's no quantitative measurement and qualitative measurement in this program.

And number three, this such a program would have very unequal impact on the egg industry. Some producers can

deal with that egg testing and diversion very easily because they have an established market, they have in line egg breaking plants, the price differential in the eggs they produce and the liquid eggs is very minimal. So it can be absorbed.

There are farms which -- in New England which is one of the regions where we produce brown eggs. There's a tremendous price differential between brown eggs and white eggs. So, the brown egg produced in New England would be ?. They could not live with such a program unless there's conindemnification due.

I work also in Maine with increasing number of small -- one percent, this number might be increasing, I don't know -- egg producers who produce exquisite, specialty markets, organic eggs, ? And some of those farms are above the 3,000 level. None of those farms could even sustain a single flock that came back environmentally positive and would go into egg testing and diversion unless there's funding available to compensate for the economic loss.

If this is -- if we have considered this all, condemnifi- -- indemnification in egg testing and diversion program would be acceptable.

But in summary, egg testing and diversion is a logical short term approach to the problem. But the solution of the problem in the interest of long term food

safety cannot be solved from one day to another. It's a process which needs cooperation with all agencies and the industry and research community to solve some of those outstanding issues.

Thank you.

MR. LEVITT: Thank you for raising the issue of diversion. I think in the current thinking document, I think we consider this one of the more central pieces of it.

Looks like Caroline's hand just went up. And I'd also like to ask for experience from Pennsylvania.

MS. SMITH-DEWAAL: Thank you. Caroline Smith-DeWaal with the Center for Science in the Public Interest.

At this point, I am cautiously optimistic that the Government's actually doing the right thing on eggs, finally. CSPI petitioned back in 1997 on the basis of the PEQAP program, and asked the Government to proceed with mandatory regulations on the shell egg industry, consistent with PEQAP. And I think that this -- the on-farm piece of what you propose so far does, in fact, meet that, what our request was back in 1997.

I have a couple of comments in response to last speaker and then I want to move into the testing program itself.

But I think the burden -- here we're talking about

burdens. And, you know, change is always going to produce difficulty for one segment or another. In the past, the burden has been on the public to handle the food safety risk associated with shell eggs. And the -- next week at the International Association for Food Protection, I will be releasing our latest outbreak list. It includes about almost 900 outbreaks, food borne illness outbreaks.

But the second largest contributor to food poisoning on our outbreak list, which goes from 1990 to the President -- to the present, are eggs, with 170 outbreaks. And I was just looking at that list. Many of these outbreaks are quite large. I mean, we have outbreaks of 1,000 people, 200 people, quite a few over 100 or 50 people. Eggs is one of the largest contributors to food borne illness outbreaks involving 50 or more people.

So, these can be quite large. They can be also from just in looking at the list of outbreaks, from things like rice pudding or bread pudding. From foods that consumers don't typically think of as having necessarily eggs in them. Unless you're a cook, you won't know, necessarily, that raw or undercooked eggs could be in these products.

So, we've had this burden of illness for many years and it's time to change. And the burden now needs to shift back to the farm, to the egg packers and to others to

minimize and reduce that risk.

I think the egg safety plan that the President announced in December is very good by focusing on the burden of illness and saying to the industry let's do better. But the bottom line is the industry -- the industry needs to solve this problem. It's not up to the Government to tell the industry how to fix the problem. The Government can announce standards, the Government can have systems like HACCP. But it's up to the industry to come up with the solution.

The testing portion of the regulation is simply a Government -- a method for the Government and the industry to check how the process controls that the industry needs to come up with are working. And on that basis, I think that the testings that you have in this rule are very minimal.

You're asking for one test during a laying cycle. And I think that's about as little testing as you could ask for in this system. And I think from a consumer standpoint, we would like to see more testing and we'd like to -- we'd like to go beyond the PEQAP model to see if testing at different points at different weeks into laying cycle might actually reduce the burden of illness even further. 'Cause that is, after all, what we're trying to do. We're trying to minimize the risk to the public.

And right now with the requirement for 40 to 45

weeks of age for the first test, means that eggs will be going out from that flock. The same thing with the requirement for after molting. I think that the test needs to, particularly with what Judy said about the thinking two years ago with the Food Safety and Inspection Service, 25 weeks seems to be quite generous into the second molting cycle.

If we think that force molting stresses the birds and that they then are more likely to produce contaminated eggs, we shouldn't be checking right at peak production. We should be checking right after the force molting has occurred.

The other thing that, that I would like to raise -- and, again, what you've done mirrors the PEQAP model and that's what we asked for three years ago. But this issue of waiting for egg testing to show a positive before you divert.

If we know flocks are infected, why aren't we diverting the eggs right away? Why do we have to wait for a second round of tests, which at a minimum, are going to take another week or so, to show us that the eggs also are infected?

So, I would like to raise with the agencies, the issue of earlier -- diversion following environmental testing, as opposed to just egg testing.

And I think that these issues are ones that the agencies should fully outline what their thinking is in the proposed and final rules to make sure that we have the best public health and science thinking, and not just negotiations which we are aware currently going on on the hill because the egg industry, once again, took their problems to Congress instead of trying to work through their problems within this kind of a forum.

So, I want to make certain that the very best public health and science thinking goes into the final regulation, and not just a rubber stamp on something that could be agreed to because the egg industry took their case to Capitol Hill, rather than trying to work it out in a scientific and regulatory forum like this.

Thank you.

MR. LEVITT: Yes, please. From Pennsylvania.

MR. ECKROADE: Bob Eckroade from Pennsylvania, and my colleague, my other colleague from Pennsylvania may like to speak, as well.

As one of the strongest proponents of the PEQAP program in this room, I'd like to say that I'm happy with the level of approach which is being introduced here. It's not that I don't support the level of testing that we do in Pennsylvania and will probably continue to do, I think what we have to realize is the tremendous impact we're going to

have in proposing a mandated federal program on every layer house in this country. This is not a small thing to propose or accomplish.

I believe that we're looking at a long term solution here, not one that's going to be solved because we identify every infected egg that's going to be -- that we know are out there.

So, I believe that we're starting at an appropriate level. I think we're going to find ten to 20 percent of the flocks we don't now know about through this environmental testing, it will give us an opportunity to work through those problem farms, allowing the others to become more sensitized to what they have to continue to do or what they better be doing behind the scenes.

We can't impose a non workable problem because it's occurring all at one time. I honestly believe that this is going to work only because this program also addresses all of the other areas that have -- that at least the egg industry has felt have been neglected in the past. And that is the shared responsibility.

All these outbreaks you talk about and the large numbers, certainly didn't become because each egg, each person ate an infected egg. We know that the massive numbers of those outbreaks are involved with cooling of eggs, which means that somebody didn't do what they were

supposed to do.

So, in the sense that this program is going to address not only on a longer term goal in identifying those infected houses, not flocks, they'll be gone. But we're going to solve -- gradually reduce those down because people can't afford to live with the increased testing and diversion. That's the incentive not to do that.

But at the same time, if we're -- if we're causing the other food handlers and the preparation, the packers, the transportation, the identification of eggs, gradually we're going to reach a goal which I think we can hold up and be proud of. But we can't impose something, day one, that people can't live with.

So, I'm happy with this approach, this level. And think it's a good starting point. And I also believe that the industry, itself, will gradually, over time, see where they are and will impose further self-imposed restrictions, perhaps testing, and this sort of thing.

I'd like to make one comment about the molting issue because that seems to be so prevalent here based on really only, almost only some research work done by good people at the Athens Lab. And they are good researchers. But they, too, have qualified how far you can interpret the effects of molting in the laboratory situation versus on the farm.

There is a -- there is a concern, and I think we need to address that -- and I understand if I can quote from my friend, Dr. David Swain, that his laboratory is already been given extra, an extra scientist and will go back and revisit this in the real world where we'll find out whether all this additional testing and just how far we're going with molting as a concerned area.

So I am happy with your level that are proposal here. That it's not more, it is appropriate. Doesn't meet everybody's needs, but it's a good starting point. And I think, over time, we're going to achieve our goal by being realistic and reasonable with our industry and with the Government approach and involving all segments.

Thank you.

MR. LEVITT: Thank you.

MR. DEBOK: Phil Debok with the Pennsylvania Department of Agriculture.

And I guess I just wanted to add on to what Dr. Eckroade and Dr. Opitz had said. I'm looking at this from the standpoint of someone that's had a fair amount of experience in managing quality assurance programs at the farm level. And what I think's doable and what isn't doable. And my thoughts may not be shared necessarily even by the poultry industry in Pennsylvania. At least the members of the poultry industry that represent the larger

producers.

Now, I realize that the exemption on sales from the standpoint of the on-farm production is intended to exempt the little guys from regulation under this rule. The reality of it is, and I can only speak for Pennsylvania, is that many, if not all of the small producers at some time or another during the year, do sell eggs that go through a third party. So they would be covered now.

If you're talking about producers over 3,000 birds, you're talking maybe 300 or a little bit more in our state. And if you're talking about smaller producers, it gets up close to 3,000.

Now, the idea of getting federal fingerprints on 3,000 chicken growers in Pennsylvania, at least in the short term, is a little bit daunting. And I think we need to step back and look at what our goals were here, and that was reduction of SE related illness or egg related SE illness by 50 percent by the year 2005.

Our production, if you're looking at less than 3,000 birds, that represents less than one percent the production in Pennsylvania, like Al Pope said. It's more like .7 percent. And, yet, what we're looking at is at least, I'm guessing, 60 to 80 percent of our effort is going to be directed toward seven percent or seven times per percent of production. That just doesn't seem very cost

effective to me. And it also runs the risk of making the program right off the bat so top heavy or so heavy that it's liable to fail initially.

Three hundred -- three hundred flocks working with them is doable. Three thousand on a short notice or on, you know, in the next couple of years of getting them on line, I have serious reservations about that.

And then the other comment on a single test, looking back through our data on PEQAP, it looks like you pick up, you know, roughly 75 percent of your flocks, your environmentally positive falls on that single test.

Now, whether it's at 30 weeks or it's 45 weeks, whether it's the end of lay, you know, that may be somewhat immaterial as to whether or not you can pick them up. But I think from the standpoint of identifying a problem flock and in the context of reduction of the problem by 50 percent in the year 2005, I think the single test is probably adequate in that context.

MR. LEVITT: Okay, I -- somebody over at the mike wants to speak. But just before we get to you, is there anybody else at the table that wants to speak, either to the issue of frequency of testing or to diversion issue? Both of them have kind of been interspersed with other.

Yeah, okay, please.

MR. OPITZ: I'm Mike Opitz. I just wanted to, to

respond to some of the comments made.

The egg industry, for example, in New England, has not been involved in any ? situation in the last 12 years. However, the egg industry has, on its own, spent millions of dollars to deal with said issue. That they have been responsive and responsible to the consumers. I just wanted to point it out.

The other clarification, when we test poultry house environments and become positive, a flock is not necessarily infected. It only means that that flock is at risk of becoming infected. So, we have to be sure about that.

MR. LEVITT: Thank you.

Yes, please. Identify yourself, if you would.

MS. FANELLI: My name is Mary Fanelli with United Poultry Concerns. And in regard to the force molting issue -- can you hear me all right?

MR. LEVITT: Yes.

MS. FANELLI: Oh. Okay. In regard to the force molting, there's been a vast amount of research done on this in field, as well as in the laboratory. Ten years -- over ten years ago, the Pennsylvania Pilot Project of three contributing factors to salmonella, implicated forced molting and aged birds. Which are birds that have been forced molted as contributing to this problem.

USDA's own research has shown forced molting to be a significant contributing factor. FDA was petitioned two years ago to prohibit this practice. Now we're told we're going to have more research and we're going to look into ways of revising the wording of this letter that FSIS has noted that salmonella is a contributing factor. This doesn't give a lot of faith to your good will and good efforts and genuine intent on preventing this problem.

It is up to industry to prevent, to solve their own problems. But it's also up to Government to prohibit industry from using practices that are known to contribute to this problem.

And I'd like to know what research is going to taken be regarding forced molting and what direction is the agency going in.

MR. LEVITT: Is there anybody here who's able to address the kinds of research? Okay, Bob Brackett, if you can come up, find a microphone.

MR. BRACKETT: Bob Brackett, FDA.

In fact, there has been a lot of research done on force molting and other stress factors on shedding of salmonella enteritidis. The problem, and this was brought up by Dr. Eckroade, is that what has been seen in the laboratory, does not necessarily correspond to what's been seen in the field. And, in fact, they are -- that is USDA

ARS is proposing to do research specifically on that issue to find out exactly what happens in the field in real life.

That is, if you do force molting, does it actually result in more eggs being infected with salmonella enteritidis. And in addition to that, to find out alternate methods of molting that could be used that might, in fact, reduce that risk.

MR. LEVITT: Okay, thank you.

First, Mr. Pope and then Mr. Beard.

MS. FANELLI: Could I just respond to that comment, first?

MR. LEVITT: Sure.

MS. FANELLI: Thanks. Forced molting has been suspected for decades and known for at least the last decade through USDA research to be a contributing factor. And to say that we're going to begin research now, looking into this, doesn't show good intent on your part, you know. Industry should be prohibited from continuing this practice until it can be shown to be safe. That's the only responsible way to address this issue.

MR. LEVITT: Thank you.

We had two comments over here.

MR. POPE: First, on the one, I want to address Caroline's statistics. And I can only say that even if I --

MR. LEVITT: You need to identify yourself.

MR. POPE: Pardon?

MR. LEVITT: You need to identify yourself again.

MR. POPE: Oh, Al Pope, United Egg Producers.

I want to address the statistics a little bit because it's always been a bugaboo and I don't take issue with Caroline, necessarily, on what she uses. But it seems like we all use some statistics that are going to be in our favor. And I've been going to CDC's since 1988, since the first release was made. I been there about every quarter since 1988. And I think we've provided due diligence on this. We've also tried to provide at each of the public hearings, a good, solid input, we hope, with statements and leadership that we hope was positive.

On the outbreaks, I've got 1988 CDC tells me -- I mean, these are not mine. That we have 48 outbreaks. The average number of people were ten that were involved in those 45 outbreaks. In 1999, there were 44 outbreaks. The average number of people were 15.

So, I just don't know where -- it's very hard for all of us, you and me, to make decisions when there's this tremendous disparity in really what's happening out there. So, I think this is a key component that we need to certainly, that will help us make decisions.

The other thing is that I have made the statement on behalf of UEB that if force molting was proven to be a

higher risk of producing higher contamination of food, as it relates to food safety risk, that we may have to end that practice. And I've said that very sincerely.

So we have gone about very diligently, I think. We have a number of projects that are already underway that are attempting to do two things. One is is it a higher risk. We have two newly funded projects that have just been approved by the American Egg Board, and I'm glad we can coordinate ours with ARS or FDA, whoever is doing those.

And the two challenges are, number one, is it a higher food risk or is it not a higher food risk. That's number one.

Number two is, and I be honest with you, I'm pretty encouraged. We have a scientific advisory committee on animal welfare, and they have given us some suggestions and we are doing some research projects on force molting without feed withdrawal at all. So, those are under way.

But each research project, unfortunately, like all research, is 18 to 24 months, especially when they're going through a molt.

So, just to update on where we're at.

MR. LEVITT: Thank you. Yes. Charlie Beard.

MR. BEARD: Charles Bear, U. S. Poultry and Egg Association.

Addressing the molting issue, I come from a

research background and I used to be at the lab where the USDA research on molting is currently being done by Dr. Holt.

One of the real challenges about SE research in poultry, it's very, very difficult in the laboratory to produce, reproduce even the most simple things. It's almost impossible to evaluate vaccines because you have great difficulty infecting chickens and getting them to lay internally contaminated eggs.

The same is true with getting chickens infected to lay contaminated eggs after they're molted. Dr. Holt is having to inoculate those birds with about either ten or a hundred million salmonella enteritidis cells to get them infected. So, when you do laboratory studies, you're very limited in what you can do with that information.

We're also providing some funds from our association to Dr. Holt because we want the answers.

Unfortunately, down the road if it's found that molting increases the shedding in eggs beyond a time when you could reasonably divert those eggs -- say, if they increased egg shedding for three weeks, those eggs could be diverted. But if molting is ever taken away from the industry, just some rough calculations, we're going to have to have about a third more, 30 percent more hatchers, 30 percent more breeder flocks.

You're going to have to kill many more male chicks at the hatchery because you only save the female chicks. There's going to be a significant environmental impact. You're going to have those additional hatchers, additional breeder flocks. And instead of hen living for over two years, two and a half years, you're going to end that hen's life at the end of that first lay.

So, they're going to be some negative spinoffs. Not only from an economic standpoint to the producer, they're going to be environmental impact spinoffs and there's going to be more animal rights, animal welfare impact because you're going to be killing that many more male chicks.

MR. POPE: Sorry, I left out one thing, too. And I do need to -- I'm sorry, Al Pope, United Egg Producers.

And this is -- this is from Peter Holt doing the research. Besides a letter that he sent saying that he wouldn't support claims that were made based on his limited amount of research, we have some lines of defense. And one that's really, we need to focus on some more, is the potential from vaccines.

This is a project that he's doing now. The birds were vaccinated pre-molt twice two weeks apart by spray. The growing period would replace these vaccinations. The work was performed this way. Birds were then put into a

molt and challenged with SE.

The vaccine reduced the transmission of the SE challenged strain from bird to bird, reduced the level of challenged strain in the intestine, the seca and completely eliminated the challenged strain from ovaries, liver and spleen.

In other words, the vaccine prevented the SE challenge from moving from internal tract, the liver, spleen, ovaries and presumably to the eggs.

So, these are things that we have to look at, you know, that are tools that, that we have available. Or will have available.

MR. LEVITT: Okay, thank you.

Caroline Smith-DeWaal.

MS. SMITH-DEWAAL: Thank you. Caroline Smith-DeWaal.

I have, I guess, one final question that I didn't bring up before. How is FDA planning to enforce this on-farm program? Specifically, the agency testified several years ago that they had really just a handful of inspectors. And in further conversations with the agency, it appeared that they had fewer than five and maybe as few as two people looking at shell eggs.

What is the current status of your program? Are you asking for more inspectors? This is not -- well, the

states, and some states, in particular, have done a good job. We do not support shifting federal inspection responsibilities wholesale to the states. And I really want to know how you plan to address this.

MR. CARSON: This is Lou Carson, FDA.

Our current plans are to seek additional appropriated funds in the time scale that we've already outlined, and let me just go over that now.

We're looking to propose standards in 2000 and to try and finalize those in 2001, with implementation over 2002 to 2003.

During 2001, we would be seeking state contracts with those state agencies already covering egg safety in their states or establishing new relationships with those state entities.

The states would be both inspecting against and enforcing the Food and Drug Administration regulations. So there would be consistent, nationwide standards. And we recognize that this will require extensive training, audit, process to insure that there is consistency nationwide.

So, that's how we're planning to implement the standards.

MR. ECKROADE: Bob Eckroade. I just had one small comment to make about the molting issue. I believe that the plan by requiring additional testing will rather rapidly

identify those flocks if they were negative to that time. If you molt, you're going to have to have another test. And if you molt twice, you're going to have two more tests. And in a very rapid way you're going to much more quickly focus on flocks that have environmental contamination, and therefore, will more rapidly identify those farms that are having a problem.

So, I think there's some built in additional testing here that's not going to be required if you choose not to molt.

Thank you.

MR. LEVITT: There's a hand over here and then I'll come back over here.

MR. WALTMAN: In reference to the previous question, I assume that companies are going -- I'm sorry, Doug Waltman, Georgia Poultry Laboratory.

MR. LEVITT: And, I'm sorry, which previous question? They kind of run together sometimes.

MR. WALTMAN: Ms. DeWaal.

MR. LEVITT: Okay.

MR. WALTMAN: I assume that the companies are going to be able to write their own SOP's and HACCP, including the components that are listed. Who's going to certify that company A's program is adequate and comparable to company B?

MR. CARSON: In the case of FDA on-farm -- this is Lou Carson, FDA. I failed to follow even my own instructions.

In the case of FDA's on-farm standards, we are setting forward regulations and industry will need to follow those regulations. Our intent is to inspect each facility that are covered by those regulations on an annual basis.

And as we mentioned, to look at records, determining whether they have followed through on that, implementation of those standards and how the program that they've put into place is working.

A question was asked previously concerning the mays and the must of the on-farm standards. For this current thinking meeting, we're putting forward what may be in that -- in those regulations. But upon the proposal and the final rule, there will be musts as part of the program.

MR. LEVITT: Yes, over here.

MS. FANELLI: Mary Fanelli, United Poultry Concerns.

Just to reiterate, it hasn't only been in lab research that's been done on force molting. The Pennsylvania Pilot Project ten years ago identified both force molting and age flocks which are the result of force molting as two of the three contributing factors to salmonella. So, it's been known for well over a decade.

That force molting is a contributing factor to salmonella.

And in response to Charles Beard's comments, it's up to industry to produce a safe product that's also environmentally responsible and humane. So, this is industry's responsibility. It's up to Government to insure that they do that.

What I see in this plan is basically intervention approaches rather than prevention approaches. For example, in addition to the force molting issue, the use of salmonella negative feed, but what is being done to prevent -- to produce salmonella negative feed? Is there any plans to prevent diseased birds and litter and other salmonella contamination being rendered back into feed?

That's what we need to clean up these problems, is to prevent them. And I don't see that happening in this plan. And we know what the problems are, we've known for a long time, and they're continuing to be ignored.

The agency is continuing to fail to address these problems in a responsible manner.

MR. MATTEIS: Rich Matteis, Pacific Egg and Poultry Association. I have laryngitis, so I hope I can activate the voice activated microphone.

I'm a bit confused as to whether we're on the clarification part of the meeting or on the public statement part of the meeting. I have a clarification question.

MR. LEVITT: We're on the on-farm part of the meeting.

MR. MATTEIS: On-farm. Okay, so they're running together, I guess is what we should say.

MR. LEVITT: Right.

MR. MATTEIS: With regard to testing and diversion, I'm unclear -- I'm perhaps slower than most, but I'm unclear as to what eggs are going to be diverted when there is a fine. You know, what -- is that going to be confined to the entire operations, specific house? I don't think that is clear from the document.

Additionally, how long must eggs be diverted and when do they no longer have to be diverted? Now, I think that's a true clarification question.

MR. LEVITT: Good questions.

MS. BUCKNER: Rebecca Buckner, FDA. What am I answering? Oh, how -- what eggs have to be diverted. I'm sorry, couldn't remember the questions.

Eggs that have to be -- you define -- we've -- we think we're going to define flocks as based on birds in a house. And so you'll be diverting eggs from a particular flock that you got the positives on.

As far as how long you have to divert, we will be putting into place protocols for you to test off diversion, but until you test off diversion, you will be diverting for

the life of that flock.

MR. MATTEIS: That was birds from a house would be a flock, is that what you said?

MS. BUCKNER: Right. A lot of it depends on how you define in your biosecurity plan what the separate entities are.

MR. LEVITT: Yes.

MR. BEARD: Charles Beard, U. S. Poultry and Egg.

On the subject of diversion, I was reading the voluminous minutes of your last hearings in Sacramento and Columbus, Ohio last evening. And I noticed that the Hawaii representative was very concerned because they have no pasteurization capability out there. I also read that California had a very limited pasteurization capability.

So, it concerns me that diversion may be a very easy word to put into regulation, but a very difficult thing to implement in some situations. And I wondered how you were going to deal with that.

The other question has to do with compensation for the losses that could be incurred from diversion.

When this program is implemented and the processor realizes that these people must divert their eggs, the free market situation is going to be bent and the seller of eggs, because they must divert, could be in a very difficult situation. There can be great economic impact. You will

probably end the operations of many of these producers, depending on their situations.

Other producers that have their own pasteurization capability, it won't even cause a hiccup. They're already pasteurizing eggs, and they'll just divert those positive houses to pasteurization. It's already running smoothly for several large companies, as we speak. It's been a very effective way of dealing with the problem.

But for those companies -- you talk about a level playing field, and I know I've heard that and read that throughout the minutes, we're going to have a level playing field. You're not going to have a level playing field because some producers don't have the option for in-house or with intra company diversion. Where other companies do.

And so that concerns me. Have you thought about compensation? Is there any possibility that can happen? Or what are you going to do when some of these companies start folding when they have to take the hit because the processor will only give them half the value of the egg?

MR. CARSON: Lou Carson, FDA. Thank you again for bringing up points that have been raised in our public meetings.

Yes, we are aware that the egg breaker industry is not uniform across the country. And that in certain places, such as Hawaii, there is no egg breaker operation.

We are trying to come up with, and we will be consulting with Hawaii and others to see what other alternatives may exist. But, again, we're looking for this to be implemented in 2002 and 2003. I think if these rules go forward, we're looking that industries will actually be started that can figure into this process.

So, I don't know that it's a foregone conclusion that no other egg breaker operations will exist in 2002 that could compensate where they do not exist today. We recognize it as a gap, currently, and we do need to try and deal with that. But we believe that our goal for public health and improved egg safety, demands that we have some alternative to putting those eggs into commercial flow.

So, we would appreciate any comments that you have on how, or other alternatives to diversion of this type.

The other comment that you made, and it was raised earlier, also, at the public meeting, actually in Ohio, had to do with indemnification. We in HHS do not have authority to indemnify, so we would have no authority nor funds to offer for condemnation.

MR. LEVITT: And if I could just add, though I think probably everyone here fully understands the whole point of this, is provide the incentives so that we don't have these problems. You know, the goal isn't to see how many positives we can find and how many we can be diverted.

Indeed, the goal's the opposite. The goal would be to try put some controls in place so we're not finding these positives. But I think, fundamentally, we have to look at the public health goal. I don't think any producer wants to label their product that says these products contain SE, use at your own risk.

So, I mean, that's the kind of balance that we have to look at. What are the preventive steps that we can reasonably put in place that are going to meet the salmonella reduction goals? And as Lou said, give industry enough lead time so you can look forward to how is that going to change our world and what do we have to do to accomplish that.

MR. BEARD: This is Charles Beard, U. S. Poultry.

I appreciate the need to protect the public health, and so does the industry and its quality assurance programs have been very effective through the years. And I think you can give them a lot of credit for the progress that's been made in the reduction of human illness. That's not my point.

My point is regardless of what we do and how good the industry does it, there are going to be positive flocks. I think we've got to be realistic about this. There's not going to be any magic bullet. We're almost getting regulation ahead of the research.

So we don't know all we need to know about salmonella enteritidis. So, I'm confident there're going to be some positive flocks regardless of how well the farm is operated, how attentive the management. There're going to be positive flocks.

And there're going to be positive flocks in situations where they don't have pasteurization alternatives except to go out on the open market. And they're going to take a real hit on the open market. Because the pasteurizer already has ample product coming in.

So, I'm just concerned about that and I wondered if there was any way that some sort of compensation -- not complete compensation. Not make it profitable for them to divert eggs. But at least get them in a situation where they could survive to clean the place up and see if they could turn it around.

MR. LEVITT: Thank you. Caroline?

MS. SMITH-DEWAAL: Thank you. Caroline Smith-DeWaal, Center for Science in the Public Interest.

Just to -- I can't resist commenting on Charles' statement because the bottom line here is that eggs from infected flocks are currently overvalued in the market. They -- the cost of those eggs is being borne by consumers in the form of illnesses, pain and suffering, sometimes deaths, lost work, medical costs.

So, there are costs associated with SE infected eggs in the marketplace today. They just happen to be borne not by your producers, but by the consumers who have the bad luck of hitting one that isn't fully cooked, or maybe using one, inadvertently, in a Caesar's salad because they just didn't know that these eggs aren't really being regulated for safety right now.

I think that, that Mr. Levitt, you hit the nail on the head. The key to these regulations for us is that they provide an incentive for the industry to solve this problem. And diversion, compensation for diversion, we strongly object to that concept because it's doesn't provide adequate incentives.

I understand that the industry will be facing change and that's going to be hard, but the job of the trade associations who are sitting around this table, as well as the research scientists, is to do the best you can to help prepare all of the producers, maybe not just your members, but even the little guys who can't afford the annual dues. To prepare each and every one of them to survive and thrive under this new system.

And I think the trade associations have a responsibility here. You're the ones in the room. We know you can go to Congress. Well, maybe you should spend less time going to Congress and more time going to the field and

talking to the little guys who may face the kind of difficult transition to the new system. And I would urge you to do that. That's your job.

MR. LEVITT: Question over here. And then if I'm looking at my watch, everybody has been very engaged, but you may not realize it, two hours goes by quicker than you think.

So I think we'll take this one comment and then we will take about -- it says a half an hour. I don't know that we need a half an hour break. But I would say about a good 15 minute break which always extends just one or two minutes.

But we'll try to take this one question and then we'll break up a little bit.

Please.

MR. CRAWFORD: Good morning. My name is Jerry Crawford. I'm counsel for the New England Poultry Association, a trade group, I suppose, though I've never gone to Congress, so far as I can recall.

A couple of observations and a question.

I was listening to Mr. Beard and Dr. Opitz before talk about the potentially disproportionate impact from the diversion half of testing and diversion. Dr. Opitz referenced the fact that there hasn't been a trace back to New England in I think he said 12 years. And, yet, the same

testing and diversion rules would purportedly apply on a nationalized basis. That's, in fact, one of the goals of your efforts thus far.

And I think this is particularly frustrating as we look ahead, given the different regional dimensions that diversion could cause. And especially because as I listen to people on both sides of every issue that's been discussed this morning, the one thing there's uniformed agreement on is that science is very much in a state of flux on all of these issues.

We don't know here today what precisely the impact of forced molting is, and we don't know precisely in the field, as opposed to in the laboratory. And we could go right down the list. There's a lot of uncertainty. And a great deal of the uncertainty focuses on an issues that I don't think has been mentioned yet this morning. And that's the impact of vaccination. And so this is my question.

If our common goal is the reduction of SE, and if in 2001 or 2002 it becomes apparent, scientifically, that SE could be reduced more by vaccination than by testing and diversion, do you intend for your rules to be flexible enough to accommodate changes in approach that result in the maximum reduction of SE, as opposed to simply resulting in the enforcement of your original view without regard to what is very fast changing science in this area?

MS. BUCKNER: Yes. Rebecca Buckner, FDA.

Yes, certainly, we intend for the rules to be flexible enough to accommodate changes that happen over the next five or ten or two years. I think you'll see when you see the rule that for every requirement there is an option for an equivalent effective requirement. And, certainly, if in two years vaccines prove to be the magic bullet that everybody's looking for, certainly we would use those.

MR. CARSON: This is Lou Carson, FDA, as well.

Just to re-enforce what Rebecca has said, we look on the on-farm standards as being progressive. We would look for research and risk assessment that is being updated and being conducted today to help inform us how to do things better in the future.

I think Bob Eckroade said it earlier. That this is a good starting point. And that's what we're looking at this program as a starting point. It's not the end point. We know we need to learn more about salmonella enteritidis and the laying cycle and in the egg. And as we do that, we believe these rules will compensate and accommodate those new technologies, whether vaccines, or other, to make the goal that we're all searching for, which is reducing food borne illness.

MR. CRAWFORD: Thank you.

MR. LEVITT: Thank you. With that, I think we

will take a break for about 15 minutes. We can regather about five minutes of 11.

(Whereupon, a brief recess was taken.)

MR. LEVITT: Thank you very much. Having had a very, pretty extensive discussion on the on-farm part, we thought that we would proceed after the break, and I'll pass the microphone back to Maggie Glavin. In doing so, I'll simply make one point for re-enforcement.

From the folks doing the transcribing, especially those that are coming to the microphones, could you again please say your name slowly and who you're from. And probably wouldn't hurt if you repeated it once.

For those at the table, they have name tags that can kind of identify us. But, again, just help for the transcribing of the meeting.

And I'll turn over to Maggie Glavin.

MS. GLAVIN: Thank you, Joe.

The part of the farm to table chain we'd like to move to now is the shell egg packer and egg products processing. And I think we can do those two together since the, the design that was presented this morning is parallel for the two segments of the industry.

So, with that, if there are questions of clarification, we can start with those. And as I suspect will happen, since it happened earlier, we will also sort of

mix in comments and concerns and suggestions, and, particularly, plaudits for those things that you really like in our proposal. So ---

That good, huh?

Caroline?

MS. SMITH-DEWAAL: Seeing it's -- it's Caroline Smith DeWaal, Center for Science in the Public Interest. And seeing as I'm going first and don't have all my notes totally organized, hopefully, you'll let me ask questions that come up as the discussion goes on, as well.

I have another couple of questions dealing with this issue.

The first one is who exactly is in charge of shell egg packing plants? There seems to be a little shift in jurisdiction here that -- and I just like to hear from the agencies what, who is going to be regulating egg packing plants. Not pasteurization facilities, per se, but actual packing plants.

MS. RIGGINS: Judy Riggins, FSIS.

FSIS, under the Egg Safety Action Plan has responsibility for packers. And I'm not sure where the confusion arose. When you said that things seem to be shifting, well, what did you exactly mean by that?

MS. SMITH-DEWAAL: Judy, in 1997, CSPI authored a report, and at that point, it appeared as though all FSIS's

responsibility only extended to pasteurizing --

MS. RIGGINS: Right.

MS. SMITH-DEWAAL: Egg products facilities.

MS. RIGGINS: Right, but the decision was made at the time that the safety action plan, the Egg Safety Action Plan was published, that the agencies agreed and the departments agreed that FSIS would assume responsibility for packers under that plan. And we -- am I answering that question?

MS. SMITH-DEWAAL: Yes.

MS. RIGGINS: Under the --

MS. SMITH-DEWAAL: What -- if you have a facility where you have both laying and packing going on on the same site, like some of the very large egg packing houses maybe in Ohio and some other places, who regulates those? How would you divide --

MS. RIGGINS: Our current thinking is that the on-farm standards would be those that would be proposed by FDA. The packer requirements would be those that would be proposed by FSIS. That we would work out a way to reduce redundancy. That there might be common plans for in-line operations, and that we would work out a way to verify the requirements of both FDA and FSIS by, by being efficient with our inspection resources.

So, we -- but with regard to the authority, the

statutory authority, if that's what you're asking, FDA would have the authority on-farm and FSIS would have the authority at packers.

MS. SMITH-DEWAAL: And I want to ask the same question I asked the FDA, how many inspectors do you have and will you need additional resources in order to expand your reach to all shell egg packing plants?

MS. RIGGINS: We are looking at all of the options to use resources. We do intend to request that amount that we would need in order to carry out adequate inspection. But the, the details of verification inspection have not, we have not thought through. However, we would have adequate coverage -- let me explain.

Under the Egg Products Inspection Act, the verification inspections at the packer would occur quarterly. At least quarterly is the language that's in the EPIA. So it is not continuous inspection as we currently have in egg breaking and pasteurization plants.

So, we are looking at all of the options to use inspection resources to effectively carry out the verification activity and to reduce redundancy so that we don't have a number of different inspectors going in and that there's a coordinated approach.

So those -- we -- I hope I'm answering your question adequately.

MS. SMITH-DEWAAL: You are.

MS. RIGGINS: We don't have every, you know, every detail worked out.

MS. SMITH-DEWAAL: What role would, if any, would AMS inspectors have in the shell egg area?

MS. RIGGINS: We have discussed the idea of using AMS inspectors to do the verification activities. We're aware that there are concerns about the use of AMS inspectors. And, therefore, as I said, we are looking at all of the options.

MS. SMITH-DEWAAL: I want to shift to a different point and that has to do with the repacking issue. And as many people in this room will be aware, several years ago, Dateline did a report on a practice, a little known until then, practice in at least one shell egg packing facility, and who knows how many others given the regulatory structure, whereby they were taking eggs which had been previously packed, rolling them out onto a line with fresh eggs that had come just out of the laying facilities, and repacking these old eggs and these new eggs together. And as a result of that, Secretary Glickman immediately issued an order saying that they wouldn't -- the AMS would no longer allow the practice of repacking eggs that had already gone to retail.

The problem arose that not all the eggs were eggs

that had gone to retail. Some of the eggs which were repacked with, together with fresh eggs and given a new XP, Exp date, had just been sitting in the cooler of this facility for two or three or even more weeks. And then they were being brought out of the cooler and repackaged with fresh eggs and given a new date.

The proposal that I see here with your current thinking, seems to contain a significant gap, in that these eggs that are coming out of the coolers will still be allowed to be repacked and given new dates. And that the only eggs that the ban on repacking applies to are those which have left the facility, gone to retail and have been shipped back. And I think that that is not addressing the problem that was outlined in the Dateline piece adequately.

MS. RIGGINS: Do you want -- or, Vickie, do you want to elaborate on that?

MS. LEVINE: Since I don't -- Victoria Levine, FSIS.

I don't have our current reg text in front of me. Yes, it'll be the shift to retail sale. And there's also going to be, I believe, a 30 day requirement. Yeah. Once an egg is processed and packed, it will be stamped with, I believe we're calling it an expiration date of 30 days. Once that egg is over 30 days old, no matter where it's been sitting, it cannot go to, for retail sale. It's got to go

to an egg breaking facility.

So, if these eggs have been sitting in the cooler for two weeks, they can go for retail sale.

MS. SMITH-DEWAAL: Could they go back to the line for repackaging?

MS. LEVINE: I don't know, I'll have to think about that.

MS. SMITH-DEWAAL: I raise this issue because we have an AMS issued regulations as a result of this AMS -- as a result of this Dateline show and Secretary Glickman's very timely announcement following the Dateline piece. I mean, we had no problem with USDA's response to the piece, but we have filed numerous comments with the agency, trying to bring up the fact that what you're proposing doesn't address the problem because you're taking stuff out of -- you know, it doesn't address the situation where they take stuff out of the cooler and reput it back on that line for repackaging.

And in talking to the producer of that piece, he indicated to me that much of the -- much of what he documented was the practice of taking it back out of the cooler and rolling it out on that line with the fresh eggs, and not the limited practice of bringing it back from retail.

MS. LEVINE: I know -- Victoria Levine -- that our

intention, I believe, is that the eggs don't get a second chance at getting dated. Now, maybe what we have right now doesn't quite say that, but I think that's the intention. So we're going to take this under advisement and think about it.

MS. SMITH-DEWAAL: Thank you. 'Cause we've raised it in written comments, but I'm still not sure it's gotten through. So, I'm feeling better today that maybe you -- you understand the gap that I'm talking about. Thank you.

MS. GLAVIN: Okay. Yes?

MS. BALDWIN: I just --

MS. GLAVIN: Could you identify yourself? Thank you.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture. I just want a clarification.

Are you saying from the date of pack, so is there any limit on how old the eggs can be at the time that they're first packed?

MS. LEVINE: Victoria Levine. I think it is the date of lay, not the date of pack.

MS. BALDWIN: So the expiration date would be 30 days from the date --

MS. LEVINE: Of lay.

MS. BALDWIN: Of lay.

MS. GLAVIN: Yes, I'm sorry, I didn't see you

there. Thank you for --

MR. HUGHES: I'm Danny Hughes, I'm representing National Egg Regulatory Officials.

I have a question or a comment to follow up with Ms. Riggins concerning who would actually be conducting the on site inspections on these quarterly visits.

The comment that I'd like to make is that with AMS, which incorporates over -- well over 50 percent of all the surveillance work, maybe even 80 percent, most all the surveillance work done quarterly now is with cooperative agreements between the states and AMS. And the surveillance visits now are all made by shell egg inspectors and not the USDA graders. That's in a plant.

So, I guess I'm just concerned what kind of problems could be that you feel like you may have to address in order for AMS to go ahead and conduct these follow-ups through the cooperating state agencies.

There's not a marketing aspect to the surveillance inspection or the inspectors doing the work.

MS. RIGGINS: Am I understanding you to say that in certain states, state inspectors conduct the surveillance or in all states, states conduct --

MR. HUGHES: Most the states.

MS. RIGGINS: In most the states. And is that under contract with AMS, or is that --

MR. HUGHES: That's correct. Um-hmm.

MS. RIGGINS: Okay.

MR. HUGHES: And it's all under, under supervision by the federal state supervisors and the Washington office. So, as far as uniformity, it's uniform across the nation. We're all under the same guidelines and under the same type of supervision.

MS. RIGGINS: Okay. Well, what we would -- what we would want to do would be to work with the states and AMS and FDA to figure out what the best approach is. If they're already state inspectors who are in the packing plants who are conducting surveillance, then one option would be to, to use the state inspectors.

We would -- you know, as Lou Carson mentioned, we, we do want to have -- and I think Rebecca also mentioned it. We do want to have a, a very comprehensive training effort so that we are training FDA, FSIS, AMS and state inspectors together so that everyone is understanding the same set of underlying values that this set of rule makings represents. And, also, that we have a common understanding of how we're going to implement it.

So, -- I mean, one option, yes, is to have the state inspectors conduct the surveillance. We would, you know, do it under contract. And how we would do that would, you know, we'd have to figure out the logistics to that.

But, yeah, of course that would be -- that could be an option.

MR. HUGHES: Well, it just makes sense. I mean, and we're talking about duplicating of services.

MS. RIGGINS: Right.

MR. HUGHES: And we're already there each and every quarter.

MS. RIGGINS: Um-hmm.

MR. HUGHES: And more often if necessary to do follow-up visits.

MS. RIGGINS: Um-hmm.

MR. HUGHES: And we're already trained. So many of us with 20 and 30 years experience in shell egg inspection, both at retail, including restaurants, nursing homes, hospitals. And then we go into surveillance where we pull samples of all the products. And to be trained as we would expect to be trained -- because no one looks for uniformity any more than the National Egg Regulatory people. We believe in uniformity and we work close with AMS and would be with FDA or FSIS, or anyone else we're associated with to get uniformity nationwide so that everybody's on the same playing field.

MS. RIGGINS: We're looking forward to working with you. As Mr. Levitt said, we want to build on what currently exists, not undo, you know, what good has been

done. So we -- this is definitely, you know, our intent.

MR. HUGHES: Okay, thank you very much.

MS. GLAVIN: Yes.

MS. BALDWIN: Deanna Baldwin, Maryland Department Agriculture.

On that same issue, would that mean, then, that like these new requirements, would they become part of the quarterly visits that are already being done to enforce what's in the Egg Products Inspection Act? I mean, are we talking about two separate visits or some combination of one visit that's going to take care of everything that's in the Egg Products Inspection Act?

MS. RIGGINS: I don't know what the current surveillance visits involve, but to the extent that we are adding food safety requirements that address issues that are not addressed by the current surveillance inspections, we would be incor- -- we would expect the verification of those food safety requirements to take place.

They could be done at the same time. I mean, to go in twice, you know, in a quarter wouldn't necessarily make sense, even, in terms of, you know, use of resources.

So, the verification for the food safety requirements could be done at the same time.

MS. GLAVIN: Okay. Over here.

MR. ANDERSON: Kenneth Anderson, North Carolina

State University. This is a clarification question.

Based on what was stated here by Rebecca Buckner -- and this relates in to processing, as well -- refrigeration of eggs held for more than 36 hours after lay will be 45 degrees. Okay.

And the second thing. If you look at the AMS regulations now for shell egg processing plants, the eggs have to be washed at 90 degrees or 20 degrees warmer than the warmest egg. If you take a 45 degree egg and throw it into 90 degree water, you're going to increase your checking, thermal checks of those eggs tremendously.

And what I'm wondering is is with the institution of this type of regulation, does that allow for processors to alter the egg wash temperatures to fit a, an egg wash temperature that will not result in increase checking, which can increase microbial contamination within those eggs.

MS. LEVINE: Victoria Levine. Yes, it will.

We are going to have a performance standard for pre-processing holding, cooling, whatever you want to call it. There will be probably a limited amount of growth possible. And you'll have to have a process that would insure that any growth would not be more than that. And then we're going to have a performance standard for washing and so on and so forth. There's a process.

Again, we're not going to require certain

temperatures, certain, you know, sanitizers or anything like that. Bottom line is when your egg comes out at the end, it's got to be -- well, it's got to be visibly clean and all of those things. I'm not going to say SE free or anything like that, but the idea is that you can -- you can do pretty much what you want as long as the end product is not adulterated.

MR. ANDERSON: Thank you.

MS. GLAVIN: Yes.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

If you're saying visibly clean, does that mean, then, there would not be any testing at the plant level, at the packing plant level? That the process would just be that it's going to be visibly clean at the end?

MS. LEVINE: Victoria Levine.

At the moment, that is our thinking.

MS. BALDWIN: So, if it were contamination then from the wash water that was not visible, it would not be a performance standard for that?

MS. LEVINE: No.

MS. GLAVIN: But do you want to talk about the performance standards and what needs to be behind them?

MS. THALER: Actually, the issue would be instead of focusing on the -- oh, Alice Thaler, FSIS.

The point of the performance standard is not to focus on how an individual packer would handle the eggs. The details of every step. But to state for them what they have to accomplish. Obviously they can't use dirty wash water and accomplish the performance standard which is going to state what is the impact of your process on the egg relative to salmonella enteritidis. So, that's the point of a performance standard.

Visibly clean, you just don't get it visibly clean and you're home free. Visibly clean because that's already in the, you know, EPIA. Plus, you have to meet a performance standard for the bacteria that we're concerned about. So, it would be up to the processor to figure out how do you accomplish that, where's the scientific information behind my process where I can withstand an audit and show that the way I handled the egg was appropriate without getting to the detail of the, dictating ph temperature and what combinations.

To allow more flexibility for the research that's ongoing now in alternate methods to cool, alternate methods to wash so they can be used as long as they produce a product that's not adulterated.

MS. BALDWIN: In -- would be only when you go in to do a regulatory visit to see if they're in compliance with this plan, would then the only validation would be that

they have a process that the science is there and they have the records saying that they followed this, there would not be any, anything else.

MS. THALER: If you follow the way that we've been handling meat and poultry, it's the issue of, first, are they following their plan, do they look like they have scientific evidence behind what they do. And at some point, there will be a validation step for a broader overview of what they do and does that actually accomplish what they think they're accomplishing.

But a routine visit generally is are they saying what they said they would do, do they have the documentation that appears to support what they're doing.

MS. BALDWIN: Will there be any standards for the operating procedures? Like the standard SSOP's. At the beginning, is there going to be anything outlined as what's required for that, or will that be part of what the plant would do? They would develop those, also.

MS. THALER: Right. I mean, SSOP's right now in the regulations is generally stated what has to be included in there and what you're aiming to achieve. And then for their individual process, they decide how, how they're going to achieve this level of sanitation that they target in order to meet the performance standard.

If you haven't, we can -- if you've been following

what we're doing for meat and poultry, it's going to be very similar. So, if you're not as familiar with that, then you might be able to review some of the information that's out there.

MS. GLAVIN: Caroline?

MS. SMITH-DEWAAL: On this same point, though, in the meat and poultry HACCP system, we have -- there is a Government verification check, a microbial check. At least in slaughter plants and some processing plants.

So, I think the point -- I think it's a very valid question of whether there is a need for some type of Government and industry -- actually, in that system, you also have industry microbial verification checks using E. coli, and then a Government verification check using salmonella.

So, I think there may be a question about whether you need some type of similar verification check that both the Government and the industry are doing.

FEMALE SPEAKER: Mr. Pope?

MR. POPE: Yeah. Eggs products plants -- Al Pope, United Egg.

In developing the performance standards, the industry is nearing the end of a four year project on pasteurization of shell eggs, and two questions I have.

One is will the results play a major role in the

development of some of those performance standards, number one. And, number two, what log kill will the performance standards require or are you looking at now?

MS. LEVINE: Victoria Levine.

We haven't finished the actual standards, themselves. We -- so we don't have the log kill yet.

If you submit the data to us, then, you know, sure, it will be considered, and ---

MS. GLAVIN: Over here? Oh, I'm sorry, Dan, did you have --

MR. ENGELJOHN: Yeah, just -- this is Dan Engeljohn with USDA.

I did want to just follow that up in that in order to move forward, we have conceptualized how we want to establish the performance standards based on what we deem to be the worse case of the pathogens that would be in the liquid egg products offered for pasteurization. And from that, derive a performance standard.

And the way our performance standards work for meat and poultry and as we would like them to work for egg products, would be that if you have mitigation strategies throughout the farm to table continuum, that you can incorporate and integrate into a system. You would be able to take advantage of that and have a lower lethality in order to achieve the same level of safety.

So, we believe that the performance standards will accommodate clean eggs coming to the processing facility with lower lethality, but achieving the same safety.

MS. GLAVIN: Yes.

MS. CURTIS: Pat Curtis, North Carolina State University, and I wanted to comment on the procedure or performance standards for egg, shell egg processors versus meat processors.

I worked for many years since before SSOP requirements in the meat processors and worked with the meat processors in trying to meet those. And I have also worked at the same time with shell egg processors. And those two operations are very, very different. The equipment in those operations are very, very different and what can be expected for SSOP's.

And looking at what's in the regulations there and trying to fit it into an egg processing plant, particularly a shell egg processing plant, is, is going to be very difficult in some places. And in the process standpoint, from the egg washing, we're talking about recycling wash water in there, which is, I guess, you might want to say something similar to a chiller water or something. But we have requirements for performance standards like zero fecal. In a processing plant, are we going to have something like wash water standards in the egg, in the shell egg?

I mean, it really varies without -- just saying we're going to set performance standards for shell egg processing leaves a lot open and we don't really know what to comment on if we don't have a little bit clearer picture on those processing performance standards for shell eggs. Because those could be very critical, whether you're talking about small egg processors or large egg processors. And how that process works.

MS. GLAVIN: Is what you're asking for that the proposal be very clear as to what those are so that comment can be --

MS. CURTIS: Right. If you don't know what the performance standards are, simply saying that you're going to have a HACCP plan, essentially, for shell eggs like you do for meats, doesn't really tell you anything because there's too much difference between meats and shell eggs.

MR. WOOD: Yeah, I'm Rich Wood with FACT and I just like to second that, and not from a consumer perspective, but from a perspective that FACT also has a nest eggs project where we have a number of egg farms that go to a couple of processors and packers. And I'm really getting nervous about the kind of definition that they need to have to be able to effectively participate in this program. And, you know, they're doing a fine job now.

But I would hope that -- and I don't know what

your plans are, but I would hope that there be some technical expertise that would be provided to these processors and packers so that they could develop performance standards that would not become the weak link in the chain of food safety that we're trying to put together here in that process.

MS. LEVINE: Victoria Levine.

We will be providing compliance guides to small producers and processors so they'll have materials to work with.

MR. WOOD: And how would that happen? Rich Wood, FACT.

How will that be communicated or conveyed to the packers? That's probably too far down the line, but, I mean, is it going to just come in the mail and we got to make sure they open the mail? Or --

MS. RIGGINS: Judy Riggins, FSIS.

I had said earlier that we intend to build on the network that we established during the meat and poultry HACCP implementation. Which is a group of land grant colleges, as well as state organizations, state entities that we send the materials to and then they basically get the materials to the small and very small producers.

So, we will have an all out effort to make sure that we get all of the packages in the small and very small

plant effort, we put together a package of a workbook of VNR or VCR tape, along with guidelines and the model plans so that people would have the kind of information and assistance that they needed in order to develop their SSOP's and their HACCP plans.

The -- we also entered into cooperative agreements with the schools to actually hold workshops so that producers could come in and actually learn together, you know, in the classroom and ask questions in each other's presence so they, you know, they had a better understanding.

So, we intend to have a very comprehensive effort to provide information to producers or packers, in our case. FDA will be doing it for producers, we will be doing it for packers. But to make sure that we've got a network in place that will get the information to the packers and producers and will adequately provide them with information and a way for them to get feedback. So that when they have a question, they can get to someone who can actually answer their questions, and answer them in a way that's practical for their particular situations. Because we understand that a lot of this is, you know, is going to be tailoring it to the situation on a particular, in a particular packing facility or on a particular farm in the case of producers.

So, we intend to do that.

MS. GLAVIN: Yes.

MS. BALDWIN: Deanna Baldwin, Maryland Department Agriculture.

Back on the exemption, I just for clarification, when it's saying -- are you saying that persons who must register with FDA are exempt from registering with FSIS?

MS. GLAVIN: Separately.

MS. BALDWIN: Okay. But they -- when I asked before, I wasn't thinking about this because she said these people that were exempt are exempt from all the requirements. But when you get to like an in-line producer, an in-line producer -- sorry -- then, would they register with FDA? Would they then have to comply with FSIS's requirements?

MS. GLAVIN: The answer --

MS. THALER: Alice Thaler, yes.

I mean, basically, this is where it gets little confusing because FDA has the on-farm part and we pick up at the packer and on. So, we have to have a coordinated effort so people know, first, who they're responsible to. But, yes.

MS. GLAVIN: Over here.

MR. WALTMAN: Doug Waltman, Georgia Poultry Laboratory.

I have two questions concerning performance standards. The first is USDA has conducted two liquid egg

surveys, and over a course of several years, the incidents of SE actually increased. Explanation was not a negative, but a positive because it showed that it's possible that more eggs are being diverted to that market.

If that's the case, then, on one hand we're telling companies to divert eggs if they're positive from the farm, and then over here we've got some kind of performance standard against SE. How is that going to take place?

MS. GLAVIN: Dan?

MR. ENGELJOHN: This is Dan Engeljohn with USDA.

The intention, again, as we establish our performance standards, was based on what we believe the published literature would show is a worse case. Taking all the information available as to what would be the highest levels of salmonella enteritidis, as well, as other pathogens of concern in liquid egg products.

If, in fact, you have a significant control over the ingoing quality of your liquid egg products such that you know you don't have high levels of pathogens in those diverted eggs or you have relatively fresh diverted eggs, then you may be able to establish a lower lethality, but achieve the same level of safety.

So, again, we're basing it on what we know to be the worse case in published literature. If, in fact, we

find from new baseline data that the levels have changed and that there are additional pathogens of concern, then we would will reassess our performance standard to ensure that it addresses all pathogens of concern and would result in a safe finished products.

MR. WALTMAN: My second question is from what you're saying, then, you're going to quantitate and not just the qualitative result?

MR. ENGELJOHN: I'm sorry, this is Dan Engeljohn. From the baseline study that we intend to do will be a quantitative enumeration.

MR. WALTMAN: You're going to quantitate the SE in the salmonella in that liquid egg?

MS. ENGELJOHN: Sorry, correction here. Martha?

MS. WORKMAN: Not SE. And the reason is is our test does not target SE, it targets salmonella . And then we will seral type the salmonella species. And if we find SE, then we will ?

MR. WALTMAN: But you will quantitate, you'll get a numerical value?

MS. WORKMAN: For salmonella species.

MR. WALTMAN: No, I'm -- I want this very clear. It's not a positive or negative, it's a ten cells per millileter. Or is it a positive, negative?

MS. WORKMAN: No, we will enumerate.

MR. WALTMAN: Thank you.

MS. GLAVIN: Caroline?

MS. SMITH-DEWAAL: Is there a zero tolerance for salmonella --

MS. GLAVIN: Would you identify yourself?

MS. SMITH-DEWAAL: I'm sorry, Caroline Smith-DeWaal, Center for Science in the Public Interest.

Is there a zero tolerance for salmonella in pasteurized egg products?

MR. ENGELJOHN: This is Dan Engeljohn with USDA.

The EPIA defines processed egg products and pasteurized egg products which would be a product which is free of viable, harmful micro-organisms. It doesn't specify a particular organism. And so for that reason, we would consider a pasteurized egg product to be free of or at least no detectable levels of harmful bacteria.

And if I could follow up. To make it consistent with what we did with our performance standards for ready to eat meat and poultry products, we established that based on a lethality, or in the alternative, a probability of survival. That there would be no greater than a certain probability that there would be more than X number of organisms left in that product.

Because we realize you can't have a, an absolute free product, but you can certainly reduce that down to a

level to where there's very low probability of survival.

MS. SMITH-DEWAAL: But to get back to the previous question, and I'm probably way over my head here, but you were talking about 10 organisms per millileter. Is that in the finished product? Okay, thank you.

MR. POPE: Al Pope, United Egg. And we're the recipient, we represent the further egg processors and they enforce a zero tolerance on our egg products plants.

MS. GLAVIN: Other -- there we go.

MR. OPITZ: Mike Opitz, University of Maine.

Just a minor, a minor point concerning registration of the small egg producers who sell directly to the consumers. You have the request of registration of all those people.

I was just wondering whether you are prepared for volume. I'm just talking about Maine. We may have something about one and two thousand of those producers. We have about half a percent of the population of the U. S. So, these numbers could escalate.

What, in turn, would be the benefit of those producers to -- from this registration? Because many of those people are very afraid. And there comes a letter from FDA here you have to register. So they are afraid of what is the consequence.

MS. GLAVIN: Can I ask FDA to handle --

MS. BUCKNER: Rebecca Buckner, FDA.

We are thinking that we will register on the small producers who sell directly to consumers so that we can provide them with educational materials. We would make it very clear that they are not under any obligation to have an SE risk reduction plan, or anything like that. So, that would be the benefit to them of registering.

And registration is simply telling us who you are and where you are. Very simple.

MS. GLAVIN: Yes.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

With the registration, then, would there be any kind of identification? Because I see if you're selling directly to egg products that you don't need to comply with the same requirements as someone that's going into the table egg market. So, is there going to be some kind of system in that registration to identify which ones are able to do which?

MS. BUCKNER: We -- Rebecca Buckner, FDA.

At this point in our thinking, no, we will not specify that people tell us whether they're sort of the strategy 1 or strategy 2 simply because people could be changing their minds all the time and then they would constantly have to be telling us that they changed their

minds. So ---

MS. BALDWIN: Would it then be up to the egg packer to make sure that the person that's producing eggs for them is in strategy 1 if they're going to the the table egg market then?

MS. BUCKNER: Yes.

MS. GLAVIN: Over here.

MR. SHIRK: Good morning. James Shirk with the Penn Egg Poultry Council.

I had a question concerning the expiration date and the 30 days. Now, is that -- was I understanding correctly that you said that's 30 days from lay, not 30 days from process?

MS. LEVINE: Victoria Levine, FSIS.

I think it is from date of lay. We're putting in a new definition which AMS has which we don't have, so we're putting it in. We're defining eggs of current production. And I'm pretty sure that that's from date of lay.

MR. SHIRK: My second question concerns labeling. Is there any indication of what this label is actually going to read? There have been some preliminary things that had a little language that I was more concerned about. If it's going to be similar to the labels that go on meat and poultry, which is much more generic label, I think that is appropriate. But do you have any sense of where that's

going?

MS. LEVINE: Victoria Levine.

Are you referring to labels on shell egg cartons?

MR. SHIRK: That's correct.

MS. GLAVIN: It's FDA.

MMR. LEVITT: That's an FDA issue. I'm afraid I have to give you a procedural issue, a procedural answer, which simply is say is that the reg isn't out yet. It's in its final stages of review. We have tried to take into consideration the various comments that have come in, but I think you going to have to wait and it's kind of beyond the scope of this meeting.

MR. SHIRK: Thank you. I have one final thing, if I may.

Under the pasteurization process, is -- it's noted that most of it is out of shell or the eggs are broken and then pasteurized. Is there any provision for eggs that are in shell for hard cooked? Is that a provision of pasteurization?

MS. LEVINE: Yes, Victoria Levine.

We're going to have a performance standard for in shell pasteurization.

MR. SHIRK: Okay, thank you.

MS. GLAVIN: Yes.

MS. BALDWIN: Deanna Baldwin, Maryland Department

Agriculture.

Is what you're saying about this expiration date, you're going to adopt exactly what AMS is using in the voluntary grading program right now? Am I understanding that right?

MS. LEVINE: Victoria Levine.

MS. BALDWIN: Thirty days is the current production and then you can put a 30 day Exp. date on anything that's of current production?

MS. LEVINE: Yeah. Yeah.

MS. GLAVIN: Okay. I -- it looks like we're -- oh, okay.

MS. BALMER: One question. Marilyn Balmer, FDA.

In your survey, are you considering doing bacillus as an organism since there was an egg associated, liquid egg associated outbreak due to bacillus?

MS. WORKMAN: Yes, we are discussing that. I did not have it on the list 'cause that is very current, current thinking

MS. GLAVIN: Okay, it looks like we're ready to move on to the retail section, and so I will turn this back over to Joe and let him decide whether he's going to let us go to lunch or not.

MR. LEVITT: We'll see if we can't do this before lunch. And if we can't, we'll do part of it before lunch

and since lunch involves retail, we'll do it after lunch, too.

The -- I think everybody remembers we go through the farm to table continuum to retail to provisions that were outlined earlier. You know, in a nutshell, basically try to take what is in the food code as pertains to eggs, put it in these regulations.

But, again, as we've done before, if we could start with questions for clarifications and then onward to comments on that section.

Yes, please?

MR. ECKROADE: Bob Eckroade, University of Pennsylvania.

Are the proposed retail standards going to be law, or do they continue to be recommendations that have to be incorporated in each state?

MS. BUFANO: Nancy Bufano, FDA.

They will be law. Er, excuse me, regulation.

MR. LEVITT: Are there questions for clarifications? Yes, Caroline.

MS. SMITH-DEWAAL: This may go beyond the scope of this meeting, but is that for all retail food code regulations or just the ones dealing with eggs?

MR. LEVITT: No, just the ones dealing with eggs. The broader food code is, you're right, a broader issue

beyond the scope of this meeting. But the idea here is take those that apply to eggs and put them in this regulation.

Yes?

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

I had asked this earlier with things that were in the Egg Products Inspection Act, but some states have requirements that are more stringent than these. Would that have any impact on those state's requirements? Can they still continue to have more stringent requirements?

MR. LEVITT: Good question.

MS. BUFANO: Nancy Bufano, FDA. Yes, if those -- those states that have adopted the food code and are enforcing the current food code or more strict requirements, those would certainly be -- these would just be the minimum, so anyone who's going over and above would be covered. Already be in compliance.

MR. LEVITT: Yes.

MR. BEARD: Charles Beard with U. S. Poultry and Egg Association. And, Caroline, we do not go on the Hill. We spend our time funding research and educating industry and having training courses.

My question concerns the provision of the food code related to at risk consumers. We've been pushing for a long time to get this made as a requirement by FDA and we've

been told year after year that they don't have the authority.

I just want to get you to restate or clarify for me that the food code relative to the service to at risk consumers is going to be a law, regulation. It's not a recommendation, it is going to be a requirement of all of those that care for at risk consumers.

MR. LEVITT: Let me try that just see if I'm clear, and please correct me if I misstate this. Right.

The food code, independent of this meeting, independent of eggs, the food code covers lots and lots of issues. And the food code is a set of recommendations. It's really, if you will, a model state code that the states adopt. And actually, I think we're up to about 40 percent that have adopted.

But those are federal recommendations for states. Here we're doing something different. Here we're saying those particular provisions as they relate to eggs and reduction salmonella enteritidis as specified here, we would make those mandatory federal requirements.

MR. BEARD: Wonderful.

MR. LEVITT: Through these regulations.

MR. BEARD: Wonderful.

MR. LEVITT: And that would apply them everywhere.

MR. BEARD: Great. Who will enforce that?

MR. CARSON: Lou Carson, FDA.

Again, FDA would establish the regulations and in almost all retail instances, we regulate through the state and the state agencies that already do inspections of the retail facilities.

So, we would establish these rules and then implement them through states. We have retail food specialists around the country that conduct audits of the state retail programs, and this would be added to those programs.

MR. BEARD: I'm thinking nursing homes.

MR. CARSON: Yes, the state, state retail units or local health departments do those inspections. We would establish these rules and then we would audit those programs.

MR. BEARD: That's great.

MS. SMITH-DEWAAL: Caroline Smith-Dewaal, Center for Science in the Public Interest.

And along the same line as Charles, I have -- I have tremendous concerns to hear the FDA is leaving this all up to the states. I'm very familiar with your program for quote, unquote auditing states for their, for their compliance with the food code, and it's almost non existent.

And, in fact, a Inspector General's report from HHS just came out with a report which was very troubling

about how FDA seems to be putting more and more of its food safety inspection responsibility on the states with less and less oversight.

I think the FDA needs to have a significantly improved inspection force if they're going to take on this job.

I'm always a little worried that -- that some day one -- you know, someone's going to come along to take away the issue of eggs from me as I lobby for a single food safety agency. You guys haven't done it yet because you've still got it divided up so the farms are regulated by FDA and processors are regulated by USDA and now the retailers are regulated by FDA with the states.

So, we still have this very bifurcated system for regulating eggs, depending on whether it's on the farm or going to the packing houses.

But I think FDA needs to be much more aggressive if they want to maintain their food functions at all. And I would urge them to consider giving them up to a new single unified agency, as I would also urge FSIS to join that effort, as well.

But I think if FDA wants to maintain any food functions at all, it needs to do so with a massive new request for inspection resources that are then directed towards foods, specifically, instead of having their

inspectors doing food plants one day and drug or medical or device plants the next.

Foods are simply too important to be third rate priority of a agency that's quite a few levels down from the Secretary in HHS. So, I think that relying on the states to do on-farm inspections and then to do all the retail inspections and then to protect the at risk consumers in nursing homes, is simply asking too much.

And many states do an excellent, excellent job. But some don't. And FDA needs the ability to allow the states that can do an excellent job under an audited system for enforcing federal regulations, to do that job, but to step in in years when, perhaps, state budgets are cut and state inspectors are being diverted to doing something else, which happens sometimes. Or in states which simply choose not to inspect food plants or nursing homes or school lunch cafeterias.

So, we need a much better system, utilizing the states appropriately, but not leaving the full responsibility for food safety protections at the state level.

MR. LEVITT: Other comments?

FEMALE SPEAKER: You got somebody over here.

MR. LEVITT: Oh, I'm sorry. Please.

MR. HUGHES: Danny Hughes, representing the

National Egg Regulatory Officials again.

Caroline's comments there at the end improved. I was questioning what her hang up was with states.

The state departments of Agriculture across the United States, and I can't say that each and every state has a state egg law inspection program that is active. But many, many do. And I would ask FDA to begin with all the departments of Agriculture who has an active state egg inspection program.

Where we've been inspecting nursing homes, hospitals, retail outlets and all for 20 and 30 years. There's no one out there who has the experience that we do in that end. Not FDA, not FSIS, not anyone.

And we would love to work with them and be able to, under their supervision, be able to show them all our reports, documents, make visits with us if they want to. But we can do an excellent job in the states.

Again, I would like to ask to go through the state departments of Agriculture before the state health departments in this area. Caroline did have some merit there. Where a lot of the health departments do have many, many products and activities that they do at the retail and nursing homes and all. Where the Departments of Agriculture who have much fewer products that they're involved in where they're out making day to day inspections. And we have all

the experience, if you compare it with state health departments.

So, as far as uniformity and our integrity, it -- I guess maybe it's not meant that way, but sometimes some of the comments almost reflects on our integrity. And with that, it's gets somewhat upsetting.

So, that's all I have to comment on that.

MR. LEVITT: Thank you. Somehow, I'm going to, as we say, listen between those last two comments and at least draw the conclusion there's a strong feeling that these regulations needs to be enforced and there needs to be an adequate inspection force, however situated. That there needs to be adequate funding for that program and we need to look at the right level of involvement, balance, and so forth, between the federal and the state authorities in the area.

Next, please.

MR. MATTEIS: Rich Matteis, Pacific Egg and Poultry Association. I have a question as to whether repacking will be disallowed at retail stores.

MR. LEVITT: Anybody know the answer to that?

MS. THALER: Yeah, at -- well, repacking -- Alice Thaler. Repacking, in general, that what you're saying is totally gone.

MR. LEVITT: I take that as a no.

Yes, over here then over here.

MS. BALDWIN: Deanna Baldwin, Maryland Department of Agriculture.

Would FSIS then have the authority to prohibit that at retail or will that fall under FDA?

MS. BUFANO: Nancy Bufano, FDA.

I think retail stores are under the authority of FDA. We hadn't considered repacking. I don't know that we've received any comments on repacking at retail.

MR. LEVITT: Please?

MR. MATTEIS: Rich Matteis, Pacific Egg and Poultry Association. The reason I bring it up is it is an issue, I know, in California. We passed law prohibiting the practice, but the retailers don't think that that law applies to them, and that's being sorted out at this time. They do repack, particularly when they have brokens. That, we argue, compromises the integrity of the date that you have on the container.

So, it is an issue.

MR. LEVITT: Okay, well, thank you for raising it here then to our attention.

Are there other questions just before we break for lunch? Caroline?

MS. SMITH-DEWAAL: I have an overall question. And if you want to figure it out during lunch and then we

can get back to it after lunch, that would be fine.

I want to know who does trace back. In outbreak situations, who is -- what agency -- which agency if the industry doesn't get it barred by all the agencies as they have in the past, which agency and how will trace backs of infected eggs to flock be achieved? Under this new system. And I'd be happy to take the answer after -- if you don't have it.

MR. LEVITT: I'll let Lou answer or point to the answer.

MR. CARSON: Lou Carson, FDA.

I'm going to actually call on one of my colleagues to answer that, Marilyn. But just to let you know, we established a work group of state and federal officials to help us work out the on-farm and packer, processor and retail standards. We also have a state, federal work group put together to help us develop specific trace back procedures for eggs that are consistent with other food products. And I'd ask Marilyn Balmer to talk about that.

MS. BALMER: Marilyn Balmer, FDA.

Reality is that the initiation of an investigation usually starts with a city or a county governmental agency. That, with this group, is not perceived to change. They are the ones there, they have the authority, they can investigate.

The work group involves both federal agencies, such CDC because they keep the statistics on outbreaks. It involves both FDA and state officials because most of the investigations are handled by the county or the city in cooperation with the state.

After that, yes, it comes under federal if it is an inner state involvement.

MR. LEVITT: Thank you. We have time for one more question before lunch if there is one.

MS. SMITH-DEWAAL: But which agency?

MS. BALMER: FDA.

MR. LEVITT: FDA. Amongst us, FDA. But she was saying that there's a strong state and local involvement.

MS. SMITH-DEWAAL: Can I just ask is that because USDA continues to be barred from being involved in trace backs?

MS. GLAVIN: My understanding is we are still prohibited from doing that. I haven't looked at the approps language recently, but I think it is still in there.

MS. SMITH-DEWAAL: Perhaps the United Egg Producers could get that reversed in Congress in the future.

MR. POPE: Well, you know, I would like to answer that because, first of all, the inuendo that we had one blocked, I wish I could block one. I have never been able to block one there yet. And I've been just as unhappy with

the delayed response that comes from there as everybody else. It is frustrating going in after the fact, but we do understand the tardiness and the timely -- and the untimeliness of some of these reports that come in, these health reports, we have no control over. Certainly FDA doesn't have any control over.

So, I feel sorry for them in a way. But to think that -- to think that we've blocked one is pretty ironic, you know, because we'd love to. But I haven't figured out a way to do it yet.

So, we'd like to see it revised. We'd be glad to participate in the revision of a good trace back program. We've said that a number of times. We've submitted our comments already on how we think it ought to be revised. And we stand ready to help in any positive way on a trace back. They're pretty -- they're important to us.

MR. LEVITT: Okay. I think we'll consider that the last word before we go to lunch. But before you go to lunch, I remind you of a couple of housekeeping matters.

Number one, when we come back, we'll go into the session of people that have already registered to speak. If there's anybody addition who is here who is not registered or would like to give a short presentation of five minutes or so, please register outside at the desk so we can get you on the list.

Second, in terms of eating, those that are not that familiar with the area, there, of course, is a restaurant in the hotel, but it probably cannot accommodate all of us. There is, if you walk two blocks north and two blocks east, up in that direction, at the far end, you would find Union Station with the food court and there are other restaurants you'll find between here and there that you can hopefully find some. And please ask them if they thoroughly cook their eggs because we all want them to. Okay.

(Whereupon, at 12:00 p.m., a recess was taken until 1:10 p.m. this same day.)

AFTERNOON SESSION

1:10 p.m.

MR. LEVITT: We have after lunch -- I think we should move into this session for prepared speakers. We have six people who have registered to give specific comments of five minutes or so each. I think I'll just list them in the order they signed up, for lack of a better methodology. And I'll read them all and then we'll simply go through one by one.

It is Alice Waters. Walters. Alice Walters, Richard Wood, Al Pope, John Mason, Mary Fanelli and Mark Worth.

Are all six of those people here now? Looks like most of them maybe. Okay, good. Well, then, again, we will -- we don't have a formal time -- I'm sorry, I have a question over here.

MR. MATTEIS: My name is Rich Matteis, Pacific Egg

and Poultry Association. I have sent in a request and received a confirmation from someone.

MR. LEVITT: Okay. With your permission, we'll add you as number seven.

MR. MATTEIS: Thank you.

MR. LEVITT: Is there anybody else that we did not include by accident? Okay. Let us start, then, with Alice Walters. Again, I do not have a, a timer. But if you could try to time yourself at about five minutes, and if you're going over, I'll waive or do something.

MS. WALTERS: Okay. I'm Alice Walters with the Ohio Poultry Association. And as many of you heard in the previous hearings, we've had a program since 1995 in Ohio, an egg quality assurance program. And I'll apologize ahead of time if I seem to be rambling a little bit. There's a number of points I'd like to bring out just for this group to consider as they finalize these recommendations.

First of all, we need to require refrigeration in all of the markets, farm markets and from the farm. We do require that in Ohio. It is a state law. We just probably need to make sure our communications in this area is very clear that the states are not pre-empted. And what we're doing with our state laws. Because we do require that in the state of Ohio.

Also, we seem to be avoiding the funding issue a

little bit. And I've mentioned to some of you I'm concerned about this 45 week test. Our test is two to ten weeks before the flock is removed from the house. That gives us several things. That gives us a history on the house, especially for the producers that have BMP programs that they're very stringent in following and they're very good at following those programs.

So we need to make sure that we have a history as that house comes out of production, too, for those producers, what that house looks like as they bring another flock into the house. That's very important for us in our program.

Also, I'm concerned about our state laboratory. We have a line item in our state budget that currently pays for a portion of all of this. It pays for test kits that go to producers that pays for the actual samples that are being run through the lab.

And if all of a sudden, at a 45 week sampling period, you may inundate the laboratory with a lot of eggs. And you need to be aware of that. What you're looking at these state laboratories to do. It's an AAVLD accredited laboratory. What's going to happen if a lot of eggs come into the lab? I know they don't like us now sometimes when a lot of eggs come into the lab.

So when you have every flock testing on that kind

of cycle, it's going to be very difficult. Currently, we test, we find a positive flock, that flock's eradicated. There's hardly ever any eggs going to the lab. Sometimes there are based on some circumstances. But that's going to be a question for these state laboratories.

We also need to emphasize that it's a wet clean and disinfect for positive flocks. We also emphasize in our BMP's, which are Best Manage for Practices of dry clean and disinfect between flocks in the BMP's.

We also have an auditing program that hasn't been mentioned too much here. The Ohio Department of Agriculture does go on farm to these houses, even the contract ? audits to make sure they're following the BMP's and that's during the cycle. So, how do we go into this federal program and make sure the people are following their BMP's? Is that same auditing program going to be carried over in the states that do have them? I know there's other states here that also have those programs.

Also, the vaccine program has not been mentioned too much. We just started this year with the Megan vaccines and also the bio immune vaccines as part of our egg quality assurance program. Took a lot of research before we started allowing our producers to use those vaccines in the state of Ohio, but we haven't heard it mentioned much here today. And I think you need to look -- go back and revisit that

area and look at that.

Also, I should mention on the wet clean and disinfection between positive flocks, we also have a re-inspection procedure that's conducted by the Ohio Department of Agriculture. They go into that house, they verify whether that house has been certified as being clean. They look at a variety of areas. There's a whole audit check sheet they go through there. And then that house is certified as a negative house again. And I haven't heard that mentioned here today.

The certification step for producers, we've had two training sessions currently in Ohio. Our last one was in June. Two hundred and forty producers attended those two training sessions. And I'm wondering on this certification steps if the state associations that work in this area, and also the departments of Agriculture and Health, and even the FDA in some cases in Ohio, are going to continue what we're doing with certification and with seminars. In those areas.

Retailers. We do have a non repacking feature for retailers. It just came about in the last couple of years. Similar to California's. We do have retailers that buck that system on repacking of eggs in the retail store. They continue to do it.

We also have retailers, even though we have a 45 degree ambiant temperature law in the state, that continue

to let eggs sit out, especially during the heavy period when their coolers may be full of other things. They don't think twice about letting eggs sit out.

It's very unfair to the producers if there happens to be a trade spec and that egg was mishandled at the retail level. So we probably need to really emphasize that refrigeration of eggs also on the retail level. Even though it may be in the code or whatever, it needs to be somehow communicated down to the retail level.

We need a floor place, if we could. I called for this in Ohio. We talked about an indemnification process which you're saying cannot happen. States can't do it, either. But maybe a floor can be placed on egg prices. On what we are doing with the prices of eggs and the quality, maybe we can make that a bonus, so to speak, for the folks that are going to be on this program. It's a costly program, especially for the small producer.

If you're a small producer and you end up with a total wet clean and disinfect, it can cost five to eight thousand dollars to do that. It's not an inexpensive process.

So, it's very important, somehow, we keep these small producers in business at the same time. And I know that's one of the mandates given the USDA Center by the President. And it's important we look at that. How are we

going to keep these folks in business and continue to have them do the HACCP programs and everything.

And that brings me to the HACCP challenge. What is our HACCP program going to be? FSIS really hasn't told us. I, too, work with needs plants and I know what their HACCP programs are like. And I haven't seen anything really outlined for egg plants and how we're going to go about verifying.

Are we going to have inspector in the plant all the time? You know, like we do for HACCP programs? And they're very restrictive. I hear a lot of complaints, too, about some of the meat inspection. And I'm sure some of the others do here.

So, how are we going to make that roll over into an egg processing facility when they're totally different types of the breed of cat, so to speak. So, how are we going to do that? I'd like to see that actually told to us.

You know, what are the steps going to be? What are the HACCP points we're going to have to look at? How are we going to have the verification process in those points?

It's very important for us as egg producers, and especially the egg processors, to know where those steps are going to be. They're critical control points.

And, basically, those are all my comments. Thank

you for listening to me.

MR. LEVITT: Thank you very much.

Our next presenter is Richard Wood from FACT.

MR. WOOD: Thank you.

I'm Richard Wood, the Executive Director for Food, Animal Concerns Trust, or FACT. FACT is a non-profit organization that advocates for better farming practices to improve the safety of meat, milk and eggs.

In 1984, FACT launched its model nest eggs program. Not nest run, nest eggs. That's the trademark. It's a niche mark, niche product. Our egg farms in Pennsylvania have included controls for salmonella enteritidis since 1991. And, so we feel we do have a model testing protocol where we test extensively throughout the life of the flock. And then the laying house when the house is empty and a couple of times during the laying life of the flock at 29 to 31 weeks, from 40 to 45 weeks, similar to the PEQAP program.

FACT and the Center for Science in the Public Interest have been providing leadership to a coalition that's been responding to the Egg Safety Action Plan as it's presented itself by an amendment in Congress. I'll shape my comments around a set of principles for on-farm production of the coalition believes must be addressed for there to be an effective egg safety action plan. And I'll just

summarize these points because we've talked about most of them this morning. But just so that I don't get lost as at least I leave this place.

What are the principles? First, require that producers purchase their laying hens only from SE negative certified flocks. This seems to be a given. I think most flocks -- many -- most flocks come from certified negative flocks, but -- from breeders. But that may not always be the case. That is an important beginning point for a flock. There where we have a salmonella testing protocol. The importance of chicks being free of SE at the time of placing house in the pullet house has long been recognized.

Since July, 1989, the National Poultry Improvement Plan has included a program designed to reduce the incidents of SE and hatching eggs and chicks. And several quality assurance programs also require their producers to purchase their chicks and pullets from hatcheries participating in the MPIP program or to require testing of a certain number of chick papers at the time of delivery.

The nest eggs program requires that chick paper -- chick box liners be tested prior to placement in the pullet house.

So the use of chicks and pullets from SE monitored breeder flocks should become a part of the egg safety action plan.

The second principle. Establish the best use of environmental test based on sound science. The cornerstone of an effective SE risk reduction program is mandatory environmental testing at all farms. Absent such testing, how does a producer know whether their quality assurance or HACCP plan is working?

The coalition supports environmental testing, overtesting only eggs. Environmental tests provide a more accurate picture of whether or not the flock is contaminated. Infected hens do not produce contaminated hens all the time, as Abraham Lincoln said, I think.

Furthermore, not all the hens in the flock are infected by SE at the same time. He said something like that, I think.

The Pennsylvania Quality Assurance Program or PEQAP has demonstrated that conducting egg tests after a positive environmental test is an effective protocol, and we would support this procedure, although in our experience, we would prefer that it be environmental, environmental, environmental. But PEQAP has demonstrated that testing eggs after a positive environmental test does work.

We all -- we've discussed forced molting this morning. At a minimum, farms that force molt should test their flocks after each molt. And we support that part of the protocol that's presented to us from FDA.

Third, conduct microbial tests early enough to protect consumers from contaminated eggs. The protocol must not only verify the effectiveness of the producer's HACCP plan, it must also protect the public from salmonella enteritidis infection. The test must take place early enough so that if the eggs are positive, there will be a time to -- there will be time to convert the eggs to pasteurization.

FACT has found on its farms that SE is more likely to appear at either 45 weeks than earlier, so the FDA timeframe is a valid one if there's only one test. And we wish there were more test. But if there's going to be one test, that seems to be an effective time, at least for the interim and for us to take a look at applying the best science. What other timeframes might be put in place as we proceed with this egg safety action plan and put it in place.

We would also suggest that the FDA look at the PEQAP model where tests following molt takes place at five to seven weeks following their return to feed. The timing of the microbial test must be early enough to protect consumers.

The fourth principle is that we clean and disinfect houses prior to population. We call on the FDA to require cleaning and disinfection after every flock, whether

or not there has been a positive. Even though it may not be directly related to it, SE positive in that house, we feel that that is a necessary protocol that we maintain an SE free house in the future.

Furthermore, when there has been a positive flock, disinfecting should be followed with an environmental sample, environmental test as a verification step. We follow this protocol on our nest egg farms. As a matter of fact, after every clean out we test. But at the minimum, there should be a test when there has been an environmental positive in the previous flock.

Other coalition principles not included in today's SE risk reduction plan include how the FDA will verify the effectiveness of the producer testing protocol. And we would, at some point, like to hear current thinking from the FDA at that point.

Second, we want a plan where only food safety related agencies implement the egg safety action plan, being mindful of duplication of services. Agencies such as Agricultural Marketing Service focus on egg quality issues and do a good job at that point, but not food safety concerns and they should not be involved in them.

Third, moving to an issue beyond the farm gate, the coalition also wants a warning label that describes the hazards and the steps consumers can take to prevent the

hazard from occurring. Apparently that is being addressed by regulation. That's why it's not, I guess, a part of current thinking. But it's certainly -- its implementation needs to be monitored to see what contribution it makes to the overall reduction of SE in the human population.

Other SE risk reduction components in the plan include the use of salmonella negative fee. We talked about that. We test our feed. We have our feed supplier test the feed for SE. We pelletize our feed and we've had very, very, low, since continuous of testing, we've had very low positive results in our testing of the feed. And there're other ways of other kinds of intervention, also, to reduce SE in feed that need to be explored and followed.

Finally, egg farms must use other biosecurity and rodent controls which we used to talk about a lot and know we know they work and so there's really not discussion on the table. And we also support refrigeration on the farm.

This egg safety plan is described today as a part of a continuum of food safety that surely begins on the farm. We want that to really happen. We commend the FDA and FSIS for placing the initiating point for this plan where the concern begins. On the farm.

Thank you.

MR. LEVITT: Thank you very much.

Next is Mr. Al Pope.

MR. POPE: Thank you, Mr. Chairman.

First, I'd like to take just a brief moment to thank FDA and FSIS in providing these thinking papers. I think it's one of the first times that you've done that before the regulatory process. And I just gather from everybody that they've welcomed that opportunity, as we have. We think it's a good forum and I want to thank you for that.

UEP represents approximately 80 percent of those producers who produce about 80 percent of the eggs in the United States. And United Egg Association represents those further egg processors that represent about 95 percent of all the eggs that are broken.

And I really appreciate the opportunity to speak today. And what I've done is I have done a detailed paper which is available to everybody. Because I felt we've heard a lot of the elements and I don't want to go through actually all, every, all of the elements today. I rather keep it sort of conceptually.

But I do want to thank -- there's tremendous history here. From 1988 when this guy called me up here and said to hold on to my seat, if I remember right, Charlie. And we met with CDC at that time. A lot has happened. The states have provided tremendous programs. We've all learned from those. We've learned from the pilot projects. So

those are all important.

I see John's here today, and we've learned a lot from them.

So, we were glad to get the thinking papers and we're going to be glad to be able to comment on them.

At UEP, we've felt that a national safety grading and inspection program is in everybody's interest. And I again want to point out that I know sound like a broken record, but I think it's very difficult to have an egg quality assurance program without including the grading and inspection portion of it. I'll always feel that way. And I know that we have to pursue that in a different way and I hope that we can have help from others in trying to do that. Because I think it's an integral part of food safety and in providing consumers, really, what they expect and what they deserve from us.

The egg safety action plan has the potential to move us in that direction and that kind of system. So we're very supportive. We've had some specific concerns about the plan, the proposed warning label. That was alarmous, we thought, without educating them. And while we haven't seen the final label, I think that the comments that we've heard, hopefully will satisfy our concerns there.

As strong as our concerns have been, we've tried to reach out to the agencies and to the groups that have

disagreed with us. I think we've had some success. I can tell the federal officials who are here today, that the egg producers' comfort level with the regulatory process is increasing. We've talked about that in the past and it's all farm groups are very -- are difficult to work with and it's hard to get a comfort level sometimes. I think everybody's worked hard to do that.

We have found that you're prepared to sit down with us, talk with us, reason with us, and I think that all of that's very positive. And just because we have some -- we still have, and I've heard in the room today, remaining disagreements does not mean our goals are any different. Our goals are the same.

UEP has argued, strongly, for example, that mandatory SE testing should be publicly funded. We think that the precedents from other programs support our argument. At the same time, we've been prepared to compromise on that issue. Our board has tried to be flexible and we've tried to be, have productive sessions with people on the other side of the argument.

We've learned from those discussions that consumer advocates may oppose public funding, in part, because they're afraid it would leave producers without enough incentives to do the right thing. I think the concern is, may be a bit misplaced because I think producers have really

powerful incentives to provide a safe product. But it's important for us to understand what that concern is. So, I still appreciate the concerns that are registered.

And let me make it clear. We share the same desire to provide incentives for safe production practices. We're more than ready to talk about how that can best be done. We're seeking public funding because we think it's fair and because our members are concerned about the regulatory costs that are associated with this program. As Alice has pointed out and others have pointed out. Not so they can escape responsibility for producing a safe product.

Let me give you another example. It now appears that the federal agencies agree with us on a critical point, that currently science tells us that diversion into processing channels should follow a positive egg test, not just positive environmental test. The environmental test, if positive, would trigger the egg testing. We agree with that view.

We're optimistic in other areas, too. We're hopeful that our Government will work hard and quickly to establish a revised updated trace back procedures that will be sensible and publicly available.

We're also hopeful that we can work with you on more emphasis on vaccines in a critical part of our food safety efforts. We've heard that more in the last two

meetings. And I can tell you that the field, where we're using it in the field, producers don't understand why all producers aren't doing that. Because the results they're getting are really very, very excellent. And so we need to put more emphasis on that.

Our producers supports standards of safety measure and production of processing that will build on the success. We've already achieved in reducing SE incidents by almost half since 1996. We want these standard to apply to everybody in the business, not just the few that are doing them.

We also want them to be implemented in the most cost effective way. It would make no sense for a single egg producer to have two, three or four different regulatory agencies coming in to his operation. That's why we've encouraged the agencies to use services of agencies that are already in place whenever they can.

And I would like to emphasize on this that I have had some private discussions on this with people, and it all boils down to this, in my opinion. He, who controls the money, controls the effectiveness of compliance program. If you have resources that you are paying somebody to have these done, it seems to be that it's your responsibility to make sure they're effective by controlling those funds.

So, I have full confidence that whomever you

choose to use them, whatever options you use, that's a really potent tool that will allow you to do a good job. And it can include state agencies, although we think it's important that they all work under a unified federal supervision.

Let me give you an example where I think we need to think creatively about how to avoid duplication.

A large portion of total shell egg production today is done in line. This means that production facility is physically located to a packing plant. It's one operation. But as I understand the way federal agencies divide up their responsibility, standards for the hen house will be set by FDA, while standard for the packing may be set by FSIS. In addition, FSIS may require formal HACCP plan for the packing plant.

So, it's just emphasizing the need to coordinate. I hope we can have some discussion on how extensive this plan might be and how it would relate to the practices of the hen house.

Frankly, a large portion of the quality control steps that will help us reduce SE take place in the hen house. This is true of biosecurity, cleaning, disinfecting, rodent, purchase of MPIP and on and on and on.

And, of course, important steps also take place in the packing plant, such as washing.

There may be, and I like to bring it up only after having my first, myself, been exposed to some of these HACCP seminars. There may be an imbalance of a formal HACCP plan as required for the packing facilities or the production unit. I prefer to talk about HACCP like standards. I'm also concerned about the duplicate regulation if different agencies are regulation different parts of the same operation.

Surely there's a way to make a single agency that's carrying out the on the ground job of verifying compliance.

I'm also pleased -- I saw a release just yesterday, I believe, or maybe it's right out here on the counter, of allocation of research funds that are being made available in this current fiscal year. And certainly we have some projects that we've already geared up for funding and we'd like to make sure that we coordinate those, you know, with the department so that there's not an overlap or anything.

In the egg industry, I think we have a good story to tell. I do want to say that UEP and UEA are committed to be a good positive player during this entire regulatory process. We want to work, our board and our members want to work with you, the consumers and with everyone else that has a stake in the food industry.

And we want to make a safe product even safer.

Thank you.

MR. LEVITT: Thank you.

Next is John Mason.

MR. MASON: I've been working as a food safety consultant for about five years. Before this, I was in charge of SE control program. I must say, I often ask myself why I come to these meetings because I've heard pretty much the same discussion for about ten years.

But I really don't want to talk about the good old times. I'd like to talk about viewing this problem from the point of view of action. What would I do or whoever is in charge of the program do about this situation right now with what we know, what was found in the SE project, what this gentleman is just made the list. And this discusses everything we've known going back to '92.

Now, the question is what could we have done, what should we do now. When we got started, I must -- they're people here from Pennsylvania. There was a cry they needed help and we went in to see, first of all, if we could get the positive eggs off the market while we did something about getting rid of SE.

It wasn't easy and it took time to develop the protocol and so forth, but really the protocol for a good quality assurance program existed by at least '91 or '92.

And what we've heard here today is again, I wouldn't say a rehash, but it's encouraging to see that it's now becoming part of an action plan.

I'd like to go back to the current situation and say do we have to wait for another year or two before the regulations come in and there are comments and there are trials? Is there something we can do now?

Now, I've been out of the program for a while and I may be blaming people for not doing as much as they could if they really are doing it, but I feel a great opportunity has been missed.

When I left, we were starting to embark on --

FEMALE SPEAKER: Can you get closer to the mike? We're not picking it up.

MR. MASON: We were starting to embark on really promoting quality assurance programs. Helping them get started, arranging for training.

Now, the first speaker talked about the action plan. Every, every farm is going to have an action plan, and somebody's going to go out there to find out what they're doing.

First of all, what are the guidelines? I don't see that the action plan has a specific guideline. Now, we've talked about this. The U.S.A. Chaves had numerous meetings over the five or six years. We finally came up

with something, but even that is not detailed enough.

So, anybody going into a farm would have to have some idea what the details are.

Now, when you start talking about that, you begin to think, well, how many people are going to be involved here, what kind of budget are they going to have, who's going to do it.

And I must say, looking at what's going on now, I would really recommend the program be given back to APHIS, to Veterinary Services. These are -- this is an agency has people in the field working with farmers, working with the agricultural departments. They don't really need a great deal more money or budget. They can start the program, continue it as we had it in the mid '90's.

So, I think that really rather than waiting, waiting for the regulation to come out, waiting for performance standards, we can use what we already know and start pushing.

Now, one of the things that wasn't mentioned is monitoring. You can't really have an effective program without somebody going in either from the state or from the organization itself and checking on what's going on. It's not enough just to keep records. You really have to find out if the work is being done.

Now, it's easy to talk about cleaning and

disinfection and rodent control and biosecurity. We all agree on that, even though the details are pretty difficult to enforce. But the heart of any quality assurance program is the need for testing.

Now, we've had, during the last ten years, arguments about what kind of testing, how much testing, what happens after you get a positive. Now, it's obvious that if you do environmental testing, you can be pretty sure that they're going to be some positive eggs. But, really, environmental testing isn't all that good.

We found out that there were flocks that were negative at one time and positive again. So, one test may not be enough.

So, the thing is somebody has to be there. Somebody that's epideamologically trained to deal with this, to go and help the farmer about what the findings are, when to test. You may have to test at the very start of a program, an egg laying program because you've got chicks that are coming in or pullets that may be positive. You may have to test, also, when you get into molting.

Now, about molting, I don't want to talk about whether we're being mean to the birds by force molting them or keeping them in cages or clipping their beaks, or whatever. But the point is if you have an eradication, a program to test birds and divert eggs, if you're going to

molt a flock that is positive, you can divert the eggs without any more risk than you had before.

So, basically, the question is to know what's going on in your flock.

Now, my feeling is at this time it is not really possible to introduce a mandatory program that would suit everybody. My feeling is that if you're going to test, you have to divert. And if you're going to divert, there has to be some way for the producer to be able to survive under these conditions.

Now, let me give you an idea of a, a perhaps an illusionary kind of program. You have a model quality assurance program. It's the Government accepts it and there's a Government seal of approval. The producers that want to take part in this, use this seal, they will get some benefit from it because they can claim that their eggs are coming from infected flocks. And I think this gentleman is saying that with his flocks in Pennsylvania.

It doesn't mean that everybody is able to do this. But until we get to a point most of the flocks can run this kind of program, I think you're going to be forced to have to have different tiers of compliance.

Now, I don't know whether you know this, but there'll be a report soon, or you may have seen the report already, the survey of the layer industry, about 50 or 60

percent of the flocks are now doing quality assurance programs of some kind. They're already testing, and I don't think it will take much more for them to get to the point where maybe in five or six years it won't be necessary to have any kind of a mandatory program because they will have driven down the infection rate to a point where it's, it's not a public health problem anymore.

One of the things that wasn't mentioned and I think this must be in back of everybody's mind. If you put in any kind of testing program and make it mandatory, do you have the laboratories to take care of the problem. You're going to have to certify laboratories, you're going to have to set up protocols for them. This is not very easy to do, and I think this has to be done on a gradual basis.

I don't want to get really into this question of trace backs. I was in charge of tracing back flocks during my tenure about five years. We had about 300 ?. We had to investigate and there were certain number of trace backs that were involved.

My feeling is that if there's -- there're quality assurance programs that are really widely dispersed through the United States. That the main point of a trace back should be as an evaluation of the quality assurance program. You check and find out if, in fact, the eggs did come from that flock and they did cause an outbreak, why wasn't the,

the SE picked up before the eggs caused an outbreak. And if there was some deficiency, they should be corrected.

But, again, the trace backs have been used mainly as a hammer to scare the producer to get into some kind of program. That's okay, but really, philosophically, I think it should be part of a learning procedure.

Well, again, I've been going down memory lane and Al Pope is kind of a hard act to follow, but, again, I probably will turn up at your next meeting and I hope you well.

MR. LEVITT: Okay, thank you very much.

Our fifth speaker is Mary Fanelli.

MS. FANELLI: Yes, Mary Fanelli with United Poultry Concerns, speaking on behalf of our more than 10,000 members.

The basic factors contributing to SE infections, such as keeping laying hens in filthy conditions and subjecting them to inhumane treatment and unhygenic practices which promote SE, are not addressed in this plan.

Correcting these root causes is the only sensible, effective and responsible way to address the SE problem.

If the Government is genuine in its concern for public health, it should prohibit practices which have been shown to hazardous and disallow them until industry can prove them safe.

The recent approval of ionizing radiation for shell eggs is yet another stop gap measure that does nothing to address the cause of the problems, but, instead, subjects consumers to other unnecessary risks and enables industry to continue to use hazardous practices to produce eggs.

These points have been noted in great detail for years at public meetings such as this and in submitted written comments. It is inexcusable for the Government to continue to ignore them. Rather than a preventative approach, this plan essentially consists of a much more cumbersome and inefficient intervention approach which is bound to fail.

By ignoring the vast amount of existing evidence and allowing industry to continue using hazardous practices to produce eggs, the Government failed its responsibility to the public.

In conclusion, this plan does not even begin to address the real problems of salmonellosis, which are the inhumane treatment and the stressful and unhygenic practices which laying hens are subjected to. Until it does, people will continue to sicken and die from eating eggs.

MR. LEVITT: Thank you.

Our sixth speaker is Mark Worth.

MR. WORTH: Good afternoon, my name is Mark Worth. I am a researcher with the Critical Mass Energy and

Environment Program, a public citizen, and it's great to be here. Thanks for the opportunity to speak.

I'm hearing, just to start out real quick, a little bit about HACCP. I'm sure folks are aware about the recent federal court ruling regarding HACCP and meat inspection. I would certainly hope that any self inspection portion of any HACCP program associated with the egg regime takes that into consideration.

I'm sure that folks are also aware of the dismal failure of the HACCP program at some of the pilot plants in the southeast.

We, we object, wholeheartedly, to irradiation. Specifically, regarding eggs. We were alarmed that the FDA approved the irradiation of eggs on Friday, long before this egg safety proceeding has reached a conclusion.

The irradiated eggs are deficient in Vitamin A and Niacin. FDA officials admit that eggs lose 24 percent of their Vitamin A when exposed to just one third of the level of radiation the agency approved on Friday. One kilogray.

Irradiation severely disrupts the interaction between albumin, a protein found in egg whites that is essential for proper blood circulation, especially in infants, and Tripsin, a pancreatic enzyme that plays a key role in healing, digestion and cancer prevention.

The high fat content of eggs makes them highly

susceptible to lipid peroxidation, a dangerous type of chemical reaction that spawns free radicals, can initiate chain reactions in the body, destroy cell membranes and hamper the body's ability to prevent cancer, diabetes, heart disease and muscular degeneration.

Many of these recent -- there have been many recent studies on lipid peroxidation. This has been research going back some 50 years. And the problem with curbing lipid peroxidation in high fat foods exposed to radiation has yet to be solved to this day.

Radiation can cause salmonella and other bacteria to mutate. Sometimes into heartier forms. One study showed that irradiated salmonella was 9600, that's nine thousand six hundred times more likely to mutate.

A 1990 study, co-authored by Donald Thayer of the USDA, concluded that salmonella becomes more resistant when exposed to radiation. Yet, in their formal federal register filing published on Friday, FDA officials used the Thayer study to support the proposal.

In doing so, FDA officials misrepresented Thayer's findings. The FDA stated in the federal register that six strands of salmonella that they have studied, were equally susceptible to radiation. In fact, Thayer actually discovered that SE was significantly more resistant than the other five strands.

The request to radiate eggs was filed by Edward Josephson, a 40 year veteran of the radiation movement. Dr. Josephson, who's now 84 and living in Rhode Island, I believe, oversaw the U. S. Army's food radiation lab in Naidic, Massachusetts for more than ten years during the '60's and '70's.

It was during Josephson's watch that in 1968, the FDA rescinded the Army's permission to serve irradiated bacon to military personnel after it was revealed the lab animals fed radiated food suffered premature death, a rare form of cancer, tumors reproductive problems and low weight gain.

A high ranking FDA official wrote at the time, an article that few people have seen since, that it is clearly apparent that the FDA cannot conclude that irradiation of baking, bacon has been shown to be a safe process.

The FDA, when it approved the irradiation of fruits and vegetables and mushrooms in 1986, depended on seven studies to show that irradiated food was safe to eat. In every study, all seven studies, the researchers engineered the study to arrive at favorable conclusions.

In one study, the first three offspring of lab animals suffered high mortality rate. So the researchers proceeded to pump the diet with large amounts of vitamins to override these negative effects.

Three of the seven studies, as far as we can find, have never been translated into English. Yet, the FDA has ignored studies that showed the feces, urine, liver, stomach and other organs of lab animals fed irradiated food, were actually radioactive. And another study, animals fed irradiated food suffered exploding arteries. In another study, they suffered nutritional muscular dystrophy. In another study, fruit flies were born with half of a thorax and extra or missing wings.

Generally speaking, food irradiation destroys nutrients, spawns free radicals that make the body more susceptible to cancer and other problems. Mass filthy slaughter house practices and conformed carcinogens, such as benzene and formaldehyde.

Generally speaking, lab animals fed irradiated food have suffered premature death, cancer, reproductive and immune problems, liver and kidney dysfunction, low birth weight, nutritional muscular dystrophy and chromosomal damage. Many, if not most of these studies, were funded by the U. S. Government, by the FDA, by the Public Health Service or the AEC.

In one study, the problems that the animals suffered were so bizarre, the research were puzzled -- researchers were puzzled to what to do about the problem. They castrated the animals and the problems went away. I

hope that that solution is not in keeping for humans.

It's little wonder that in 1969 an article was published in the World Health Organization bulletin by researcher from the University of Pittsburgh who cautioned that we should slow down the irradiation approval process because of the thalydamide disaster of the 1960's. Yet, the WHO, as we all know, went ahead and authorized the irradiation, I believe, to this day, at unlimited levels.

Just over the weekend in Florida, irradiated meat was pulled from the shelves of two stores. One in Stewart, one in Lakeland because of poor consumer demand. And, also, we think because people are finally becoming aware about the unintended consequences of eating irradiated food.

There is, in fact, no real demand for irradiated food. There is demand for safe food. And we think that consumers want sanitation, not irradiation.

If anyone has any questions about anything I've said, we have documentation regarding every point made. You can send us an e-mail via citizen.org if you would like any follow-up.

Thank you.

MR. LEVITT: Thank you. And as I'm sure you know from the federal register notice that you cited that the FDA recently published, there is a place in there that you ought to send your concerns in writing to.

MR. WORTH: Right. We, we are planning on doing that as soon as possible. We are highly -- we -- our concern could not be higher regarding the abuse of a federal register, the bible of the federal Government administrative agencies, to misrepresent research, especially by somebody as distinguished as Dr. Thayer.

Thank you.

MR. LEVITT: Our final speaker is Rich Matteis.

MR. MATTEIS: Rich Matteis.

MR. LEVITT: Matteis, thank you. We goofed up twice. First of all -- three times. First, we forget him, then we put him at the end, then we goofed up his name.

MR. MATTEIS: So, am I owed one?

Rich Matteis, Pacific Egg and Poultry Association. Since I am vocally challenged, I will be brief.

We represent the egg industry in 11 western states. We appeared at the Sacramento meeting. I'll reiterate some of the comments we made there 'cause they appear to be not in the thinking papers. And I don't take any personal offense to it, but I just want to state it again in case the message did not come through.

First of all, I'd like to say that our industry does support egg safety. We sponsored five bills ourselves on refrigeration, labeling and handling of eggs. We supported a couple of others in the retail establishment

area and have put together and help coordinate one of the, we think, finer egg quality assurance programs in the country.

What we had stated at the Sacramento meeting is that there ought to be some recognition of those quality assurance programs that are in place. There've been reference to those plans today. And certainly some of the concepts embodied in the thinking papers are incorporated in some of the quality assurance plans. But there is no formal recognition of those plans. And we think it's more than coincidental that salmonella is on the decline at the same time that those plans are being implemented. This is certainly true in California.

It would seem to make sense, it would seem to be logical, then, to try to incorporate, tap into that resource in preparing this proposal in order to meet the objectives that you have for eliminating salmonella.

We recommended at the time 'cause we know agencies just don't like to hear people just say no, but recommend alternatives, that there should be different treatment for those facilities that are in a certified program that you approve and that are monitored by either your agency or some state or county agency.

We believe that that should be an alternative and an exception from participating unnecessarily in all of the

requirements that you propose in this plan.

A two-tiered approach, if you will.

It seems to us that that is a good way to get people to buy into the program. I am not comfortable with the answers given on enforcement and the dollars to support adequate and consistent enforcement. Not that we're digging for more enforcement, but we are concerned one of the goals is a level playing field. And unless enforcement is consistently applied, we do not end up with a level playing field.

And, so, we do have concerns in that regard.

There are regional differences with regards to both legislations, statutory requirements and egg quality assurance. And, so this proposal will have different impacts on those different regions. It will not be a level playing field.

You heard in Sacramento that in California we have precious few facilities to divert positive eggs to. And in Hawaii you heard they have no facilities. Yet, these thinking papers propose no mitigation measures for that. And we do urge the agency to consider that.

We also addressed in Sacramento the burdens on small business, which was made clear at that meeting, you have a obligation to address and we assume that you will address those concerns as you move forward.

Michael Opitz referred to some of the impacts on smaller producers, and we think they will be great. Even one positive find could put somebody out of business. And so those economic burdens certainly need to be addressed for small producers, as well as large.

With regard to some earlier discussion on this being an incentive based program, with all due respect, we would not equate a consequence of not complying with a mandate as being an incentive. Those are two different things. I just like to make that observation that this is a mandatory program, not one that utilizes incentives.

If you incorporated an alternative which allowed people to comply with the proposal by participating in a certified quality assurance program, then you truly would have an incentive based program, and that's another argument in favor of that.

It was mentioned earlier by the first speaker that the testing requirement of 45 days does not coincide with the testing requirement they have in their quality assurance program. I think it was Ohio. Same is true of California.

I won't reiterate all the aspects of our program, but ours is more in line with Ohio's toward the end of the lay. And that's something that should be considered.

In closing, I would just like to say that this doesn't appear to be a focus program. There have been no

comparative risk analysis. It is very true that in California and elsewhere in the west, there are size facilities where there's never been a history of salmonella, but where requiring or imposing the same requirements of all facilities without giving any consideration to risk, doesn't not seem to be the best use of either industry resources or of governmental resources. And, again, does not take into consideration the fact that quality assurance programs have been effective in dealing with the issue.

And I thank you.

MR. LEVITT: Thank you. And, again, our apologies for not having you signed up properly.

This essentially, I think, brings us to the conclusion of what we had set out to do today. Before Maggie and I try to summarize, I'll give kind of a one last offering.

Are there any other voices or issues that have not already been heard or voiced? That as you sat through the day and reflect, say, boy, I wish I had a chance to say that. Because as it is, we have a few minutes we can devote to that.

Yes?

MR. ECKROADE: Bob Eckroade, University of Pennsylvania.

One quick one on the diversion of eggs, which I

support, would be that in some manner they go without some red tag to the truck marked, or what have you. Our experience with the pilot program in Pennsylvania was when they went with the USDA red tag, that's when the producer really suffered financial ruin.

And I believe while it's essential that we document that those eggs are diverted, to have them go to the processing plant with some sort of label on them, will guarantee this economic loss.

So, I'd like to see our program not include some sort of a red flag that goes with the truck to the processing plant.

MR. LEVITT: Thank you.

MS. BALMER: Can I ask for a clarification on that? Would you then expect the process, the egg processing plant to not then package some of those eggs for the table egg market?

MR. ECKROADE: A real challenge -- Bob Eckroade, again. A real challenge, Marilyn. I made the assumption that when they go there, they are processed into liquid eggs. And if that's not the case, there's a problem.

MR. LEVITT: Yes. Is it additional point?

MR. WORTH: Just a question. Mark Worth, again, Public Citizen.

Is anyone here right now today who can answer a

question as to why the irradiation of eggs was approved before this process had concluded? Or is that deemed as a separate issue?

MR. LEVITT: That's really a separate issue.

MR. WORTH: Okay. Thank you.

MR. KEENER: Kevin Keener, North Carolina State University.

I just had a few comments in regards to I do a lot of work with meat and poultry processing and also egg processing, and I wanted to make a few comments in regards to that, with looking at cost and some of the things that seems to have been regards to training for the egg processing, focusing on that, not necessarily the production. But highlighting some things at least my familiarity.

With regards to meat and poultry, HACCP and the way that that was implemented, we've done some studies, some of my colleagues and I, looking at cost. And it was roughly 500,000 to a million dollars per plant increased cost. And that included additional water, additional equipment, additional employees working directly on HACCP plan and HACCP training.

And that's a consideration you're going to have to look at in regards to this. It seems to have been overlooked 'cause I haven't heard any mention of that. So,

I wanted to highlight that point.

Another point is in regards of training of whoever is going to be doing these inspections. It seemed like from my experience with the implementation of the meat and poultry HACCP, there's been some training difficulties with some of the inspectors in some of the plants that I worked with with regard to their understanding of HACCP and the approach that they take to how HACCP should operate. And so I want to highlight that. That the training program needs to be very well laid out and insure that there regulators are trained in the understanding of HACCP and HACCP principles.

The third point that I wanted to mention is in regards to alternative technologies. We've talked a lot about the existing system, but one of the questions -- and we've encountered this with some of the technology we've been working with is who's going to make decisions on that technologies, who's going to evaluate those, who do we file with, what type of a timeframe is there?

Those are questions, at least in our mind, haven't been addressed, and we've had some difficulties with some of the equipment and technologies we've been working with.

So, I would encourage you to develop some type of protocol that researchers such as myself and my colleagues can follow up.

Thank you.

MR. LEVITT: Yes.

MR. MYERS: This is T. J. Myers of the Animal and Plant Health Service, USDA.

I just want to follow-up on John Mason's comments about APHIS. And, you know, while we recognize that APHIS does not have authority on the farm in the egg production side of things, I just want to remind FDA that we do have a sizable field force of veterinarians. And as I mentioned, a number of these other meetings in the past, we do stand ready to provide whatever assistance we can with --

MR. LEVITT: Okay, appreciate that very much. Thank you.

Caroline.

MS. SMITH-DEWAAL: Caroline Smith-DeWaal, Center for Science in the Public Interest. And just one more thought before we leave.

I was -- I thought John Mason had a lot of food for thought in his comments, and I particularly like his nothing new since '92 in terms of how this meeting --

MR. LEVITT: We're going to hear that back for a long time.

MS. SMITH-DEWAAL: Seems to be repeating a lot of what we've said in previous meetings over the last few years.

Bottom line is consumers have been facing this health hazard for a very long time. Over a decade from the CDC first identified the issue of internally contaminated eggs.

You now are on a time line where you say you're going to get regulations in place and implemented by 2002, which would be ten years from the nothing new since '92 time. I certainly hope that nothing intercedes, either legislatively or politically or any other way, to delay a program that really is well past its due date or ripeness date from the standpoint of public health.

We need this program. We need it soon. And it would be better today than in 2002, but it is urgent that you speed this action forward.

Thank you.

MR. LEVITT: I think that's a good note to close on.

MR. MARINELLI: Can I --

MR. LEVITT: At great peril, Clark.

MR. MARINELLI: Clark Marinelli, FDA.

I'm with the economics group. There have been a lot of comments that have touched on the economics today. We're really here to listen and I just want assure you that we're here and we're going to be taking these into consideration. We are carefully estimating the cost of the

egg safety action plan, and will, of course, provide those estimates to central management.

So, the economic concerns are being heard and we are here. I just want to point that out.

MR. LEVITT: Okay. Thank you.

With that, I think it is time to bring this to a close. I will not try to summarize everything we've heard, but I think I would reflect on just a few things.

I don't personally have in this particular area, the ten year history, though I have heard it recited enough times. I do often like to use the phrase that I call the planets are coming into alignment. And while I'm not sure they're in perfect alignment yet, I think they're a lot closer to alignment than they were, you know, several years ago, or even a year ago from now.

I think the process we've been using in the last year has been moving the issue forward. And I think, you know, the general sense of the room is at this time to move forward and do this and do this right for the benefit of consumers.

It doesn't mean that we agree on every issue. Clearly, we don't. Some there are disagreements in the details, some there're disagreements on some fundamentals. But I think as an overall approach to say we've got to get on-farm controls, we need to have controls of the packing

and processing facilities, we need to have controls at retail. And although we're not talking about it today because we've dealt with it previously not yet out, we need to deal with it at the consumer level, also. And have really a full farm to table program on SE in order to -- in eggs in order to meet our goal of 50 percent reduction in five years.

I think that I feel encouraged again by not just the process of last year, but the level of participation, the level of knowledge in the room.

You know, a lot of times we have meetings where most of the people in the room were sent to take notes and report back to somebody else. And this is kind of the opposite. This is more like a meeting of the experts. Virtually everybody here, I think, has hands on knowledge, experience and involvement. So I think that's really added to the value of the discussion for us to move forward.

Maggie, anything else from --

MS. GLAVIN: No, I'd like to thank people for their attention and for their interest and their input. You all have been very forthcoming and I also am very impressed by the great extent to which we stayed on topic today. Not 100 percent, but we really did pretty well.

I think I picked up a number of themes, and in no particular order, and these are certainly not exhaustive, a

call for evenhanded enforcement. I think that was pretty universal. Concerns and questions about jurisdiction and overlap between and among the agencies and how those will be resolved and clarified.

A lot of concerns about available resources to put these -- resources both at the industry level and at the Government level. Questions on the extent of the repack bans. Someone raised an issue about the repack ban applying to retail, which I think was something that maybe we hadn't given as much consideration to as we might have.

A need for a Government and/or an industry verification of performance standards. A number of people raised that. A need for clarity in our proposal on what we actually are proposing on performance standards. I sense some frustration that our current thinking paper and our presentation didn't give you enough to get your hands with respect to the performance standards. And so I call that the proposal be much clearer in that area.

And just some practical issues were raised, such as the capacity of labs and scheduling lab capacity. I think those were real helpful because that's the real world. That's what we have to deal with.

And then a request that we consider perhaps moving to HACCP like standards rather than a formal HACCP plan requirement.

So those are some of the themes I picked up as the day went on. Again, they're not by any means exhaustive, but they're ones that I felt sort of wove themselves through the day. Came in and out on the various things.

I say thank you to you all. I think this has been very helpful. And we certainly are committed to moving forward with these regs and getting a proposal out on the streets so that we can enter into the official comment period. And this meeting will be an enormous help in moving us in that direction.

MR. LEVITT: Okay. Meeting adjourned.

(Whereupon, at 2:15 p.m., the hearing was concluded.)

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Washington, DC
Place of Hearing

July 31, 2000
Date of Hearing

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